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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none"> • 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 3	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

>> CCDM Detail Explanation <<

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SCDM Certified Clinical Data Manager Sample Questions (Q92-Q97):

NEW QUESTION # 92

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

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

Answer: D

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 # 93

An organization conducts over fifty studies per year. Currently each study is specified and set-up from scratch. Which of the

following organizational infrastructure options would streamline database set-up and study-to-study consistency?

- A. Implementing controlled terminology for adverse events
- **B. Maintaining a library of form or screen modules**
- C. Adopting an ODM compliant database system
- D. Improving the form or screen design process

Answer: B

Explanation:

To improve efficiency and ensure consistency across multiple studies, the most effective infrastructure solution is to maintain a centralized library of standardized forms or screen modules (e.g., CRF/eCRF templates).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), using a form library allows reuse of validated data collection modules for commonly collected domains such as demographics, adverse events, and vital signs. This reduces database setup time, enhances uniformity in data definitions, and ensures alignment with standards such as CDISC CDASH and SDTM.

While adopting ODM (A) provides standardized data exchange and interoperability, it does not inherently reduce setup workload. Improving design processes (C) enhances efficiency but doesn't guarantee consistency, and implementing controlled terminology (D) helps with coding standardization, not database structure.

Therefore, option B - maintaining a library of form or screen modules - provides the most direct and sustainable improvement for scalability and quality.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.3 - Use of Standard Libraries and Templates CDISC CDASH Implementation Guide, Section 3.2 - Reusable CRF Modules and Standardization ICH E6(R2) GCP, Section 5.5.3 - Standardization and Reuse in Data Collection Systems

NEW QUESTION # 94

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

- A. Data in incoming files are consistent with existing data in the study database
- B. Incoming files have the expected number of records
- **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 # 95

Which method would best identify clinical chemistry lab data affected by a blood draw taken distal to a saline infusion?

- A. Abnormally high sodium values in a dataset
- B. Abnormally low urine glucose values in a dataset
- C. Lab values from a blood draw with a very low sodium and very high other values
- **D. Lab values from a blood draw with a very high sodium and very low other values**

Answer: D

Explanation:

If a blood sample is drawn distal (downstream) from a saline infusion site, it may become contaminated with saline, leading to abnormal laboratory results. Saline contains a high concentration of sodium chloride, which artificially elevates sodium while diluting other blood components.

Therefore, such samples would display:

Very high sodium levels, and

Abnormally low levels of other analytes (e.g., proteins, glucose, potassium).

This abnormal pattern (option B) is a classic indicator of saline contamination.

Per the GCDMP (Chapter: Data Validation and Cleaning), cross-variable consistency checks are critical for identifying biologically implausible patterns, such as this one, which indicate pre-analytical errors rather than true physiological changes.

Hence, option B accurately describes the data signature of a contaminated blood draw.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Logical and Consistency Checks for Laboratory Data ICH E6(R2) GCP, Section 5.1.1 - Data Quality and Biological Plausibility Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Detecting Laboratory Anomalies

NEW QUESTION # 96

A Data Manager is designing a report to facilitate discussions with sites regarding late data. Which is the most important information to display on the report to encourage sites to provide data?

- A. Expected versus actual forms entered
- B. Number of forms entered in the last week
- **C. List of outstanding forms**
- D. Total number of forms entered to date

Answer: C

Explanation:

In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.

According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:

Outstanding CRFs not yet entered,

Unresolved queries, and

Pending data corrections.

Such reports help sites prioritize and address data gaps efficiently.

Option A and D are historical metrics without actionable context.

Option B gives a general overview but lacks specific site-level actionability.

Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

NEW QUESTION # 97

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