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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	• 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	• 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 4	• 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 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.

SCDM Certified Clinical Data Manager Sample Questions (Q95-Q100):

NEW QUESTION # 95
Which metric reveals the timeliness of the site-work dimension of site performance?

- A. Time from final protocol to first patient enrolled
- B. Median and range of time from query generation to resolution
- C. Time from site contract execution to first patient enrolled
- D. Time from Last Patient Last Visit to database lock

Answer: B

Explanation:
The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks - particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.
According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.
Other options measure different aspects of project progress:
A reflects overall database closure speed.
B and C relate to study startup and enrollment readiness, not ongoing data work.
Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 - Site Query Resolution Metrics ICH E6(R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Oversight

NEW QUESTION # 96
During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Statistician
- B. Quality Auditor
- C. Investigator
- D. Data Manager

Answer: A

Explanation:
The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.
The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

NEW QUESTION # 97
The Scope of Work would answer which of the following information needs?

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

Answer: D

Explanation:
The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:
The number of database builds or migrations,
Timelines for deliverables (e.g., database lock),
Responsibility distribution between sponsor and CRO, and
Budget parameters for defined activities.
Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.
Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

NEW QUESTION # 98
A protocol amendment adds three data elements to the vital signs screen and two additional data-collection time points. Which is best practice for handling changes to the form completion guidelines?

- A. Notify sites of the change without a guideline update
- B. Update the guidelines and notify sites of changes prior to implementing the change
- C. Update the guidelines and post the new version on the trial portal
- D. Rely on the revised CRF to enforce the changes without updating guidelines or notifying sites

Answer: B

Explanation:
The best practice when implementing a protocol amendment that affects CRF content or data collection timing is to update the

eCRF completion guidelines and notify sites before implementing the change.
According to the GCDMP (Chapter: CRF Design and Data Collection), the eCRF Completion Guidelines (eCRF CG) are an essential study tool that instructs site personnel on accurate and consistent data entry. When new data elements or collection time points are added, the guidelines must be revised, version-controlled, and communicated to all users prior to implementation to ensure sites collect and enter data correctly.
Simply relying on the revised CRF (option C) or updating the document without notification (option B) violates communication and training standards. Likewise, notifying sites without updating the documentation (option D) leaves insufficient reference material for data entry compliance.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.5 - Managing CRF Revisions and Site Communication ICH E6 (R2) GCP, Section 5.18.4 - Communication of Protocol Amendments and Documentation Updates FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Site Communication and Documentation Management

NEW QUESTION # 99
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 transferred to the contract research organization is not required.
- B. A general statement that all obligations have been transferred is acceptable.
- C. A description of each of the obligations being assumed by the contract research organization is required.
- D. Any written description is not transferred to the contract research organization.

Answer: C

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 # 100
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