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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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.

Topic 2	<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 3	<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 4	<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 5	<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.

SCDM Certified Clinical Data Manager Sample Questions (Q83-Q88):

NEW QUESTION # 83

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of statistical analysis methods
- B. Enumeration and explanation of data errors
- C. Clinical narratives of adverse events
- D. Rationale for the study design

Answer: B

Explanation:

The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.

According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies. Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is therefore the most relevant for review.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 84

All of the following are preparation processes the data manager needs to take prior to database closure EXCEPT:

- A. Ensuring all data expected for the study has been received.
- B. Performing SAE reconciliation between the clinical and safety databases.
- C. Ensuring study close out visits have been complete.
- D. Checking for uncoded terms in all panels that are coded.

Answer: C

Explanation:

Before database lock, the Data Manager must confirm that all collected data are complete, validated, and reconciled across systems. This includes:

Ensuring data completeness (B) - confirming all expected forms and data files have been received.

Verifying coded data (A) - ensuring no pending terms remain in coding dictionaries like MedDRA or WHO Drug.

Performing SAE reconciliation (C) - cross-checking the clinical database against the safety system for accuracy.

However, ensuring study close-out visits (D) is not a data management function; it falls under clinical operations and monitoring responsibilities. While data management may review confirmation of site close-outs, the activity itself is not part of pre-database lock procedures.

Therefore, option D correctly identifies the exception-an activity outside the data manager's direct scope of responsibility before database closure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.3 - Pre-Lock Validation and Reconciliation Activities ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Quality Control Prior to Lock FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Database Management and Lock Procedures

NEW QUESTION # 85

What are the key deliverables for User Acceptance Testing?

- A. eCRF Completion Guidelines
- **B. Test Plan/Script/Results**
- C. Project Plan
- D. Training

Answer: B

Explanation:

The key deliverables for User Acceptance Testing (UAT) are the Test Plan, Test Scripts, and Test Results.

According to the GCDMP (Chapter: Database Design and Validation), UAT is the final validation step before a clinical database is released for production. It confirms that the system performs according to user requirements and protocol specifications.

The deliverables include:

UAT Test Plan: Defines testing objectives, scope, acceptance criteria, and responsibilities.

UAT Test Scripts: Provide step-by-step instructions for testing database functionality, edit checks, and workflows.

UAT Test Results: Document actual test outcomes versus expected outcomes, including any deviations and their resolutions.

These deliverables form part of the system validation documentation required under FDA 21 CFR Part 11 and ICH E6 (R2) to demonstrate that the database has been properly validated.

Project Plans (option A) and Training (option B) occur in earlier phases, while eCRF Completion Guidelines (option D) support site data entry, not system validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing Deliverables FDA 21 CFR Part 11 - Validation Documentation Requirements ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Validation Records

NEW QUESTION # 86

Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Screening study subjects
- B. Using ePRO devices
- C. Resolving discrepant data
- **D. Training on how to log into Medical Records system**

Answer: D

Explanation:

In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).

According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.

While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

NEW QUESTION # 87

The Medical Dictionary for Regulatory Activities (MedDRA) structure is in which of the following hierarchical orders, from most specific to least specific?

- A. LLT, PT, HLT, HLT, SOC
- B. LLT, HLT, PT, HLT, SOC
- C. LLT, PT, HLT, HLT, SOC
- D. LLT, HLT, HLT, PT, SOC

Answer: C

Explanation:

The MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology used for coding and analyzing adverse event (AE) and medical history data in clinical trials. Its hierarchical structure supports aggregation, analysis, and reporting across varying levels of medical specificity.

From most specific to least specific, the hierarchy is as follows:

Lowest Level Term (LLT): The most granular term, often reflecting the verbatim text reported by the investigator.

Preferred Term (PT): The standardized medical concept representing one or more LLTs describing the same condition.

High Level Term (HLT): A grouping of related PTs describing similar medical conditions.

High Level Group Term (HLGT): A broader grouping of related HLTs.

System Organ Class (SOC): The highest level of classification, grouping HLGTs by body system or etiology (e.g., cardiac disorders, infections).

Thus, the correct order - from most specific to least specific - is:

LLT → PT → HLT → HLGT → SOC, which corresponds to option D.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.2 - MedDRA Hierarchical Structure ICH M1 MedDRA Terminology Guide, Version 26.0 - Hierarchy Overview ICH E2B(R3) Guidelines - Clinical Safety Data Management

NEW QUESTION # 88

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