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SCDM Certified Clinical Data Manager Sample Questions (Q52-Q57):

NEW QUESTION # 52
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 look up which visit PK samples are taken
- C. To find the name and contact information of a specific clinical data associate
- D. To determine the number of data transfers budgeted for a project

Answer: D

Explanation:
The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.
According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:
The number and frequency of data transfers,
Database build and lock milestones,

Quality control deliverables, and
Resource allocation for data management tasks.
The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).
Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 53
When implementing a study utilizing an EDC application, it would be appropriate to use free text fields for which of the following?

- A. Adverse event verbatim term
- B. Urine sedimentation rate
- C. Body Mass Index
- D. Date of birth

Answer: A

Explanation:
In Electronic Data Capture (EDC) systems, free text fields should be used only when a predefined list of acceptable responses cannot accommodate the full variability of input data - most notably for Adverse Event (AE) verbatim terms.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), AE verbatim terms are initially entered as free text by site staff to accurately capture the investigator's exact medical description of the event. These verbatim terms are later coded using standardized dictionaries such as MedDRA during medical coding, ensuring both flexibility and standardization in reporting.
Conversely, fields such as urine sedimentation rate (A), date of birth (C), and Body Mass Index (D) require structured numeric or date formats to enable validation, range checks, and consistency across datasets. Free text would compromise data integrity, accuracy, and validation efficiency for these structured data elements.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.3 - Use of Free Text and Coded Fields ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Structure and Validation MedDRA Introductory Guide, Section 2.3 - Verbatim Entry and Coding Requirements

NEW QUESTION # 54
A Data Manager is establishing a timeline for database lock for a 100-person study where the data have been maintained almost all clean throughout the study. All data from external labs have been received and reconciled. Which is the best estimate of the amount of time needed to lock the database after Last Patient Last Visit?

- A. A few weeks
- B. A few days
- C. A few hours
- D. A few months

Answer: B

Explanation:
For a well-maintained 100-subject study with ongoing data cleaning and completed reconciliations, the database lock process typically takes a few days after the Last Patient Last Visit (LPLV).
According to the GCDMP (Chapter: Database Lock and Archiving), the duration of the lock process depends on the level of data cleanliness at LPLV. If the study team has conducted continuous data cleaning, query resolution, and external data reconciliation throughout the trial, then the final lock steps (e.g., final data review, documentation, and approvals) can be completed in 2-5 days. However, if significant cleaning or reconciliation remains outstanding, lock may take several weeks. Since the question states that data are "maintained almost all clean," Option B - a few days - is the appropriate estimate.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 6.2 - Database Lock Preparation and Timelines ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Lock Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Lock and Archiving Procedures

NEW QUESTION # 55
Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- A. Communication Plan
- B. Data Transfer Agreement
- C. Data Management Plan
- D. Project Plan

Answer: B

Explanation:
A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.
The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.
The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.
Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 56
What is the main reason 21 CFR Part 11 requires that EDC systems maintain an audit trail?

- A. To preserve the ability for modifications
- B. To preserve source document verifications
- C. To preserve data integrity
- D. To preserve data availability

Answer: C

Explanation:
The primary purpose of maintaining an audit trail as required under 21 CFR Part 11 is to preserve data integrity. According to the U.S. FDA's regulation on electronic records and signatures, every change to electronic data must be traceable, including information about who made the change, when it was made, and what the change entailed.
The Good Clinical Data Management Practices (GCDMP) outlines that an audit trail provides a permanent, chronological record of all modifications to clinical data. This ensures transparency and allows the reconstruction of the course of data entry and modification. The regulation aims to prevent unauthorized or undocumented data manipulation, thereby maintaining the accuracy, reliability, and validity of electronic records.
The FDA 21 CFR Part 11, Section 11.10(e) explicitly mandates that systems must use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. This ensures the data remains trustworthy and defensible in regulatory reviews or inspections.
Therefore, the main reason for requiring an audit trail is to preserve data integrity - ensuring that all data captured, modified, or transmitted is authentic, accurate, and complete throughout the study lifecycle.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Data Integrity FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(e) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Integrity and System Validation

NEW QUESTION # 57
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