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Access Control - Policy and procedure that defines accessibility to a physical space or electronic source of information. The policy usually includes the concept of audit trails, either paper (ie. signature log) or electronic.

Adverse Drug Reaction (ADR) - In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions.

Adverse Event (AE) - In a subject or clinical-investigation subject administered a pharmaceutical product, any untoward medical occurrence which does not necessarily have a relationship with the treatment.

Analysis Dataset/ Analysis File - The final data set, including derived items and excluding redundant data points, which is used to perform the analyses required for safety assessment, efficacy assessment, submission to regulatory authorities, or other review. (Can be 1 or more files)

Annotated CRF - A document that maps the names of collected items to their corresponding database tables, variable item names, forms, visits and any other objects needed for someone to correctly analyze data collected in a trial. Required for someone to understand where variables for analysis originate.

Applicable Regulatory Requirements - Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

Application Service Provider (ASP) - A vendor who provides, manages and distributes software based services to customers over a network

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SCDM Certified Clinical Data Manager Sample Questions (Q31-Q36):

NEW QUESTION # 31

A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- B. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- C. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.
- D. Additional sites will likely have increased query rates since site training is occurring closer to study close.

Answer: C

Explanation:

Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.

While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2)

GCP, Section 5.1 - Quality Management and Oversight

NEW QUESTION # 32

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

- A. Rationale for the study design
- B. Description of how data were processed
- C. Description of statistical analysis methods
- D. Clinical narratives of adverse events

Answer: B

Explanation:

The section of the Clinical Study Report (CSR) most useful for a Data Manager is the description of how data were processed.

According to the GCDMP (Chapter: Data Quality Assurance and Control), this section details the data handling methodology - including data cleaning, coding, transformation, and derivation procedures - all of which are core responsibilities of data management. Reviewing this section ensures that the data processing methods documented in the CSR align with the Data Management Plan (DMP), Data Validation Plan (DVP), and database specifications.

The statistical methods section (option A) is primarily for biostatistics, and the rationale for study design (option B) pertains to clinical and regulatory affairs. Clinical narratives (option D) are used by medical reviewers, not data managers.

By reviewing how data were processed, the Data Manager verifies that the study data lifecycle-from collection to analysis-was conducted in compliance with regulatory and GCDMP standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 -

Documentation of Data Processing in Clinical Study Reports ICH E3 - Structure and Content of Clinical Study Reports, Section

11.3 - Data Handling and Processing FDA Guidance for Industry: Clinical Study Reports and Data Submission - Data Traceability and Handling Documentation

NEW QUESTION # 33

Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. Data managers write the Data Management Plan that specifies the data cleaning workflow.
- B. Data managers have access to programming tools to identify discrepancies.
- **C. Data can be viewed and discrepancies highlighted prior to a monitor's review.**
- D. The GCDMP recommends that data managers review data prior to a monitor's review.

Answer: C

Explanation:

The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality.

Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

NEW QUESTION # 34

A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial
- B. The DMP does not need to be updated as it represents the data at the beginning of the trial only
- C. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- **D. The DMP should be updated to reflect the changes to the protocol and stakeholders notified**

Answer: D

Explanation:

When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.

Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

NEW QUESTION # 35

What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

- **A. Data entry**
- B. Resolving queries
- C. Medical record abstraction
- D. Data curation

Answer: A

Explanation:

In paper-based trials, site staff (e.g., study coordinators) record data manually on paper Case Report Forms (CRFs), which are later transcribed by data entry personnel into an electronic database.

However, in EDC-based studies, the site coordinator is directly responsible for entering data into the EDC system. This eliminates the need for centralized double data entry and shortens data cleaning timelines.

The GCDMP (Chapter: Electronic Data Capture Systems) states that EDC systems shift certain tasks, including data entry, initial query response, and source verification preparation, to the site level. Yet, data entry remains the most significant additional responsibility compared to paper-based studies.

Option A (Query resolution) is performed in both EDC and paper-based systems.

Option C (Data curation) is typically a Data Management function.

Option D (Medical record abstraction) is part of source documentation, not specific to EDC.

Thus, option B (Data entry) is correct - it is the additional site coordinator duty unique to EDC environments.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.3 - Site Responsibilities and Workflow Changes

ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Role Delegation in Computerized Systems FDA Guidance for Industry:

Computerized Systems Used in Clinical Investigations, Section 6.2 - Site-Level Data Entry Controls

NEW QUESTION # 36

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