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SCDM Certified Clinical Data Manager Sample Questions (Q29-Q34):

NEW QUESTION # 29

Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- **A. List of late queries by site and summary table**
- B. Graph and summary table of clean cases by site
- C. Graph of expected versus actual enrollment
- D. Table of outstanding queries counts by site

Answer: A

Explanation:

The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.

According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.

While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.

Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site Query Management Reports ICH E6 (R2) GCP, Section 5.18.4 - Communication Between Monitors and Sites FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Query Metrics and Site Performance Review

NEW QUESTION # 30

Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. Statistical Analysis Plan (SAP)
- B. Data Management Plan (DMP)
- **C. Standard Operating Procedures (SOP)**
- D. CRFs

Answer: C

Explanation:

Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).

According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.

Other options serve different purposes:

SAP (B) defines statistical methodology, not compliance control.

DMP (C) focuses on study-specific data handling, not organizational compliance.

CRFs (D) are tools for data collection but do not enforce compliance by themselves.

Therefore, option A (SOP) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 -

NEW QUESTION # 31

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 # 32

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

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

Answer: A

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 # 33

Which document describes what study subjects expect with respect to data disclosure during and after a study?

- A. Study data sharing plan
- **B. Informed consent form**
- C. Study protocol
- D. ICH essential documents

Answer: B

Explanation:

The Informed Consent Form (ICF) is the document that explicitly describes what study subjects can expect regarding data disclosure, privacy, and confidentiality during and after participation in a clinical trial. According to ICH E6 (R2) Good Clinical Practice and FDA Human Subject Protection Regulations (21 CFR Parts 50 and 56), participants must be fully informed about how their personal and clinical data will be collected, used, stored, and shared - both during the study and in any subsequent data-sharing or publication activities.

The GCDMP reiterates that clinical data managers must ensure that all data handling practices align with the privacy commitments made in the ICF. This includes compliance with data protection regulations such as HIPAA (in the U.S.) and GDPR (in the EU).

The ICF defines the permissible scope of data use, ensuring ethical management and subject protection.

Documents like the protocol or data sharing plan may outline procedures and responsibilities but do not directly inform participants of their rights and data use expectations. Only the ICF is designed for that ethical communication purpose.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Ethics, Privacy, and Data Security ICH E6 (R2) Good Clinical Practice, Sections 4.8.10 & 4.8.12 FDA 21 CFR Part 50 - Protection of Human Subjects, Informed Consent Requirements

NEW QUESTION # 34

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