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SCDM CCDM資訊 - CCDM考試重點

隨著社會的發展，現在SCDM行業得到了人們的青睞，也有越來越多的人們想考取SCDM方面的資格認證證書，在事業上更進一步。這個時候你應該想到的是PDFExamDumps網站，它是你CCDM考試合格的好幫手。
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最新的 Clinical Data Management CCDM 免費考試真題 (Q49-Q54):

問題 #49
Which is the best reason why front-end checks are usually kept minimal, when compared to back-end checks, in a paper-based clinical study?

- A. There is no need to alert the site personnel immediately about a data issue, as the study has happened already
- B. There are approvals required to raise a Data Clarification Form which could take time
- C. Data review can be performed at a later time due to the paper-based studies being smaller in size
- D. Data entry staff should be able to enter a value into the database just as it appears in the paper CRF

答案：D

解題說明：
In paper-based clinical studies, front-end data checks (those performed during data entry) are intentionally kept minimal to ensure that data are entered exactly as recorded on the paper CRF. This principle ensures data integrity by maintaining fidelity between source and electronic records before any cleaning or edit validation occurs.
The GCDMP (Chapter: Data Validation and Cleaning) explains that data entry operators should input values as written, even if they appear incorrect or inconsistent, because the purpose of front-end checks is not to interpret but to capture data faithfully. The back-end edit checks-performed later by data managers-are designed to identify inconsistencies, out-of-range values, or logical errors that require clarification through queries.

This approach separates data capture from data cleaning, minimizing bias and preserving original investigator input. Hence, option A accurately states the rationale for keeping front-end checks minimal in paper-based studies.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 4.2 - Data Entry, Edit Checks, and Query Process ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Data Entry and Verification Processes

問題 #50
A study is using blood pressure as an efficacy measure. Which is the best way to collect the data?

- A. Measurement using existing equipment at sites
- B. Asking the study subjects what their blood pressure usually runs
- C. Measurement using study-provisioned equipment
- D. Collecting the data from the medical record

答案：C

解題說明：
When a clinical study uses blood pressure (BP) as an efficacy endpoint, the most reliable and standardized method of data collection is through study-provisioned equipment.
According to the GCDMP (Chapter: CRF Design and Data Collection), data collected for primary efficacy endpoints must be consistent, accurate, and standardized across all investigative sites. Using study-provided calibrated equipment ensures that measurements are taken under uniform conditions, eliminating inter-site variability due to differences in devices, calibration, or measurement methods.
Collecting BP data from medical records (option A) risks inconsistent timing and techniques. Using each site's own equipment (option B) introduces variability, while patient self-reports (option D) lack reliability and objectivity.
Thus, the best practice is to provision and standardize all equipment used to collect endpoint-related physiological data, ensuring regulatory-quality results suitable for analysis.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.1 - Standardization of Clinical Measurements ICH E6 (R2) GCP, Section 5.5.3 - Data Accuracy and Equipment Standardization FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Capture and Standardization Requirements

問題 #51
With the implementation of EDC, which company Standard Operating Procedure (SOP) would require updates for new procedures of handling data?

- A. Handling External Data
- B. Data Backup, Recovery, and Contingency Plans
- C. Coding Medical and Clinical Terms
- D. Data Review and Validation

答案：D

解題說明：
When a company transitions from paper-based data capture to Electronic Data Capture (EDC) systems, one of the most critical areas requiring procedural updates is the Data Review and Validation SOP. The introduction of EDC systems fundamentally changes how data is collected, reviewed, validated, and queried.
According to the Good Clinical Data Management Practices (GCDMP), the implementation of EDC introduces real-time data entry and review, automated edit checks, and electronic query management. These functionalities necessitate revised procedures to define how data validation, discrepancy management, and monitoring are conducted electronically. The SOP must specify roles, responsibilities, system access controls, and processes for electronic source verification (eSource), ensuring compliance with 21 CFR Part 11 and ICH E6 (R2) requirements.
Other SOPs such as Handling External Data or Data Backup may require minor updates, but the Data Review and Validation SOP undergoes the most extensive change because EDC technology shifts validation responsibilities from post-data entry review to real-time oversight within the system.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.3 -

SOP Adaptation for EDC Implementation FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Validation

問題 #52
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 assumed by the contract research organization is required.
- B. Any written description is not transferred to the contract research organization.
- C. A description of each of the obligations being transferred to the contract research organization is not required.
- D. A general statement that all obligations have been transferred is acceptable.

答案：A

解題說明：
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

問題 #53
In a study conducted using paper CRFs, a discrepancy is discovered in a CRF to database QC audit. What is the reason why this discrepancy would be considered an audit finding?

- A. Discrepancy not explained by the protocol
- B. Discrepancy not explained by the data quality control audit plan
- C. Discrepancy not explained by the CRF completion guidelines
- D. Discrepancy not explained by the data handling conventions

答案：D

解題說明：
In a CRF-to-database quality control (QC) audit, auditors compare data recorded on the paper Case Report Form (CRF) with data entered in the electronic database. If discrepancies exist that cannot be explained by documented data handling conventions, they are classified as audit findings.
Per GCDMP (Chapter: Data Quality Assurance and Control), data handling conventions define acceptable data entry practices, transcription rules, and allowable transformations. These conventions ensure that CRF data are consistently interpreted and entered. If a discrepancy deviates from these established rules, it indicates a process gap or error in data entry, validation, or training. Discrepancies justified by protocol design or CRF guidelines would not constitute findings.
Therefore, option C (Discrepancy not explained by the data handling conventions) correctly identifies the criterion for a true QC audit finding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Data Handling Conventions and QC Auditing ICH E6(R2) GCP, Section 5.1 - Quality Management and Documentation of Deviations FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Verification and Audit Findings

問題 #54
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那邊傳來的談話，大多數都是恭維奉承之言，這內丹的靈力也正在減少，手裏握著中階靈石快CCDM速補充著靈力，不同職業,不同需求的客戶可以根據自身情況來購買最為適合自己的的組合,找到一種最適合的做題方式,更為有效的利用自己的時間,早日取得Certified Clinical Data Manager證書。

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