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## CCDM certification exam - Part 1 Questions and answers Newest RATED A+ 2025/2026

**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 (Q131-Q136):

### NEW QUESTION # 131

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

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

**Answer: B**

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 # 132

Which of the following SOPs are required for management of an EDC system?

- **A. Change control**
- B. Management of vendors
- C. Maintenance of coding dictionaries
- D. Measurement of data quality

**Answer: A**

Explanation:

The most essential Standard Operating Procedure (SOP) for management of an Electronic Data Capture (EDC) system is Change Control.

Per GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, any changes made to an EDC system-whether to software configuration, study database design, or system functionality-must follow a documented, validated, and auditable change control process. This ensures that:

Modifications are properly authorized, tested, and approved before implementation.

System validation remains intact.

Data integrity, traceability, and regulatory compliance are maintained.

While vendor management (A) and coding maintenance (C) have supporting SOPs, change control (D) is mandatory for any system handling regulated clinical data. Measurement of data quality (B) is important but not specifically tied to system management procedures.

Thus, option D (Change control) is the correct answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.3 - Change Control and System Maintenance FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures, Section 11.10(a-k) ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and Change Documentation

### NEW QUESTION # 133

Which of the following actions is particularly important in merging data from different trials?

- A. Use of a common software platform
- B. Enrollment of investigative sites with similar patient populations
- C. Use of a common adverse event dictionary
- D. Exclusion of studies that use a cross-over design

**Answer: C**

Explanation:

When merging data from different clinical trials, the use of a common adverse event (AE) dictionary (such as MedDRA or WHO Drug) is essential to ensure consistency and comparability across datasets.

According to the GCDMP (Chapter: Standards and Data Mapping) and CDISC SDTM Implementation Guide, data integration across studies requires standardized terminology for adverse events, medications, and clinical outcomes. Using the same AE dictionary ensures that similar terms are coded consistently, allowing accurate cross-study analysis, pooled summaries, and safety reporting.

A shared software platform (option A) is not necessary if data are mapped to standard formats (e.g., CDISC SDTM). Patient population similarity (option B) affects interpretation but not technical data merging. Study design differences (option C) may influence statistical analysis but not data integration mechanics.

Therefore, Option D - Use of a common adverse event dictionary - is the correct and most critical action for consistent multi-study data integration.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 5.1 - Use of Standardized Coding Dictionaries CDISC SDTM Implementation Guide, Section 4.3 - Controlled Terminology and Cross-Study Integration ICH E3 and E2B - Clinical Data Standards and Safety Coding Requirements

### NEW QUESTION # 134

A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which of the following should the Data Manager consult first?

- A. A CDISC therapeutic-area implementation guide
- B. Data elements used in clinical registries in the therapeutic area
- C. SNOMED terms used in the therapeutic area
- D. Forms used by other sponsors in the same therapeutic area

**Answer: A**

Explanation:

When efficacy data are not covered by existing CDISC SDTM domains, the first resource the Data Manager should consult is the CDISC Therapeutic Area Implementation Guide (TAIG) for that therapeutic field.

According to the GCDMP (Chapter: Standards and Data Mapping), CDISC's Therapeutic Area User Guides (TAUGs) and Implementation Guides provide standardized data structures, variable definitions, controlled terminology, and implementation examples for specific diseases or therapeutic areas. These guides ensure consistency across studies, promote interoperability, and align data collection with regulatory submission expectations.

Consulting other sponsors' forms or external registries (options A and C) can be informative but do not provide authoritative CDISC-compliant standards. SNOMED terms (option B) address medical terminology, not structural data domain definitions.

Therefore, Option D is correct-CDISC TA Implementation Guides are the recognized primary reference when extending or designing SDTM-compliant CRFs.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 4.2 - Use of CDISC Standards CDISC Therapeutic Area User Guides (TAUGs) - Implementation Guidance for Domain Extension FDA Data Standards Catalog - CDISC Therapeutic Area Standards

### NEW QUESTION # 135

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

- A. Rationale for the study design
- B. Description of statistical analysis methods

- C. Clinical narratives of adverse events
- **D. Enumeration and explanation of data errors**

**Answer: D**

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 # 136

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