

# Real And Valid CCDM Exam Questions & Answers

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## CCDM certification exam - Part 1 Questions and answers

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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 (Q98-Q103):

### NEW QUESTION # 98

A CRF was approved by the Sponsor and development of a clinical database has been started according to the data management plan. What is the next responsibility of the Data Manager?

- A. Prepare system requirements specification
- B. Prepare a communications plan
- C. Prepare a data validation plan for the clinical database
- D. Plan the timelines to ensure a clinical database is ready before the first screening

#### Answer: C

Explanation:

Once the Case Report Form (CRF) has been finalized and database development has begun, the next primary responsibility of the Data Manager is to prepare a Data Validation Plan (DVP) for the clinical database.

According to the GCDMP (Chapter: Database Design and Build), the DVP documents all planned validation procedures - including edit checks, cross-form validations, discrepancy management workflows, and system testing requirements. This ensures that data entry, processing, and cleaning are consistent with protocol requirements and that the database will produce reliable, auditable data for analysis.

While system requirement specifications (option B) are prepared before database development begins, and timeline planning (option C) occurs during the study startup phase, the DVP is the critical next step post-CRF approval to define and validate system logic before user acceptance testing (UAT).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.4 - Data Validation Plan (DVP) Development ICH E6 (R2) GCP, Section 5.5.3 - Validation of Computerized Systems FDA 21 CFR Part 11 - System Validation Requirements for Electronic Records

### NEW QUESTION # 99

During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Expected and actual results
- B. Training requirements
- C. Reconciliation datapoints
- D. Root cause analysis of the system errors

#### Answer: A

Explanation:

When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred).

According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:

Test objective,

Preconditions,

Test steps,

Expected results,

Actual results, and

Pass/fail status.

If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing. While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.

Therefore, the correct answer is B - Expected and actual results.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

## NEW QUESTION # 100

The Scope of Work would answer which of the following information needs?

- A. To determine the number of database migrations budgeted for a project
- B. To look up which visit PK samples are taken
- C. To look up the date of the next clinical monitoring visit for a specific site
- D. To find the name and contact information of a specific clinical data associate

### Answer: A

Explanation:

The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:

The number of database builds or migrations,

Timelines for deliverables (e.g., database lock),

Responsibility distribution between sponsor and CRO, and

Budget parameters for defined activities.

Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.

Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

## NEW QUESTION # 101

Which of the following roles commonly requires data entry and update privileges in an EDC application used in a clinical study?

- A. Clinical Study Monitor
- B. Site Study Coordinator
- C. EDC System Administrator
- D. Study Statistician

### Answer: B

Explanation:

In an EDC system, Site Study Coordinators are typically responsible for data entry and updates, as they are the site-level personnel who record subject data from source documents into the electronic CRFs (eCRFs).

The Good Clinical Data Management Practices (GCDMP, Chapter: EDC Systems) outlines that data entry and modification privileges should only be granted to qualified site personnel who have completed EDC system training and are listed on the study delegation log. These users directly handle patient-level data entry and correction.

In contrast:

Clinical Study Monitors (B) review and verify data but do not enter or modify it.

EDC System Administrators (C) manage user access and configuration settings, not study data.

Study Statisticians (D) work with extracted, cleaned datasets but never have data modification privileges.

Thus, option A (Site Study Coordinator) correctly identifies the role with authorized data entry and update privileges.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - User Roles and Access Permissions ICH E6(R2) GCP, Section 4.1 - Investigator Responsibilities for Data Accuracy FDA 21 CFR Part 11 - User Access and Accountability in Electronic Systems

## NEW QUESTION # 102

According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good

Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing the algorithm for calculating the average score on the CRF
- **B. Providing the algorithm for calculating the average score in the dataset definition file**
- C. Providing CRF annotation "not entered in the database" next to the average score
- D. Providing CRF annotation AVE next to the average score

**Answer: B**

Explanation:

In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.

According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.

The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.

Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

## NEW QUESTION # 103

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