

M. Sc. CLINICAL RESEARCH
SEMESTER - II EXAMINATION, JUNE – 2026
(2025 Batch)

(CMCR516) CLINICAL DATA MANAGEMENT

[Time Allotted: 3:00 Hours]

[Max. Marks: 100]

Note: Read all the instructions carefully

Answer all questions in serial order, Draw suitable diagrams wherever necessary

- Q. 1. Objective type questions: (Attempt All)** **(10 x 02 = 20)**
 (Very short/ Short answer/ MCQ/ One liners/ Fill in the blanks/ True/False)
- a. Write two roles of Clinical Data Management System. [CO2,PO2]
 - b. Define role-based access control with examples. [CO1,PO3]
 - c. Define omics. [CO1,PO1]
 - d. Define Source Data Verification (SDV). [CO2,PO3]
 - e. What is GIGO? [CO1,PO1]
 - f. Write any two benefits of Clintrial. [CO2,PO2]
 - g. Mention any two features of Medidata Rave. [CO2,PO2]
 - h. Differentiate between soft lock and hard lock. [CO3,PO2]
 - i. How do clinical data-mining tools help detect insurance fraud? [CO1,PO2]
 - j. What is the common data checked during AE reconciliation? [CO3,PO2]
- Q. 2. Short notes / Short Answer Type (Attempt any **five** out of **seven**)** **(5 × 4 = 20)**
- a. What are the types of multicenter trials? Mention the importance of multicenter trials. [CO2,PO1]
 - b. Discuss the impact of GDPR (General Data Protection Regulation) and HIPAA on data governance. [CO1,PO3]
 - c. What is SPSS (Statistical Package for Social Sciences)? Write the steps of data preparation in SPSS. [CO3,PO2]
 - d. Define metadata and elaborate its components. [CO1,PO2]
 - e. Give an account on the working of a CIRB (Central Institutional Review Board). [CO2,PO3]
 - f. Define Medical Records Review. Also elaborate the types of surveys. [CO2,PO1]
 - g. What is conformance? Give an account on its types. [CO3,PO2]
- Q. 3. Structured Question (Attempt any **three** out of **four**)** **(3 × 10 = 30)**
- a. Give an account on the steps/strategies to maintain sound data storage and preservation. [CO2,PO3]
 - b. Discuss the general structure of SDTM and SEND. [CO2,PO2]
 - c. What is AE reconciliation? Give an account on its importance, examples, and steps. [CO3,PO2]
 - d. Role of biostatistics and bioinformatics in healthcare industry. [CO1,PO1]
- Q. 4. Long Answer/Essay type (Attempt any **two** out of **three**)** **(2 × 15 = 30)**
- a. What is discrepancy management? Discuss the types of discrepancies that arise during clinical data management. [CO3,PO2]
 - b. Differentiate between a paper CRF and an eCRF. Also design a CRF of your selected research project. [CO2,PO2]
 - c. Give an account on 21 CFR Part 11 and 21 CFR Part 1. [CO1,PO3]