

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

(CMCR511) CLINICAL TRIALS

(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)

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| a. Define informed consent. | [CO1, PO3] |
| b. Define bioequivalence. | [CO1, PO1] |
| c. Explain carryover effect. | [CO2, PO1] |
| d. Differentiate between qualitative data and quantitative data. | [CO1, PO2] |
| e. Mention any two skills required for a medical writer. | [CO5, PO4] |
| f. Differentiate between ANDA and AADA. | [CO4, PO3] |
| g. Mention any two functions of the NAITIK portal. | [CO4, PO3] |
| h. Define PSUR (Periodic Safety Update Report). | [CO7, PO3] |
| i. Define signal detection in pharmacovigilance. | [CO7, PO1] |
| j. Define CRF and mention its components. | [CO1, PO2] |

Q. 2. Short notes / Short Answer Type (Attempt any **five out of **seven**)**

(5 × 4 = 20)

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| a. Explain how ICMR guidelines contribute to ethical conduct and regulatory compliance in clinical research. | [CO4, PO3] |
| b. Discuss the components and requirements of an NDA submission. | [CO4, PO3] |
| c. Explain the delegation of duties among PI, co-PI, and sub-PI in a clinical trial. | [CO5, PO3] |
| d. Discuss the advantages and limitations of academic clinical trials. | [CO2, PO1] |
| e. Define Randomized Controlled Study (RCT) and explain its importance in clinical research. | [CO2, PO1] |
| f. Define statistics and explain its role in clinical research. | [CO1, PO2] |
| g. Differentiate between single-center and multicenter clinical trials. | [CO2, PO1] |

Q. 3. Structured Question (Attempt any **three out of **four**)**

(3 × 10 = 30)

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| a. Discuss the phases of clinical trials involved in drug development. | [CO3, PO1] |
| b. Design a protocol of your own selected clinical Trial. | [CO4, PO3] |
| c. Explain the approval process for clinical trials under the New CT Rules 2019. | [CO4, PO3] |
| d. Discuss the steps of the Mutual Recognition Procedure (MRP). | [CO4, PO3] |

Q. 4. Long Answer/Essay type (Attempt any **two out of **three**)**

(2 × 15 = 30)

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| a. What is monitoring in clinical trials? Explain its types. Also discuss auditing and inspections, highlighting their role and types. | [CO6, PO3] |
| b. Explain the various types of clinical trial designs with their advantages and limitations. | [CO2, PO1] |
| c. Explain ADR monitoring, recording, and reporting systems. Also discuss five case studies of drugs withdrawn due to pharmacovigilance. | [CO7, PO3] |