

# Question Paper

Exam Date & Time: 29-Nov-2023 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

**Clinical Research [PPR-MPP104T - S3]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

Answer the following (10 marks x 5 = 50 marks)

- 1) Explain the various approach to drug discovery and development. (10)
- 2) What are the different types of study designs in clinical research? Explain any four in detail. (10)
- 3) Explain clinical trial agreement execution. (10)
- 4) Discuss the essential documents required before starting the clinical trial. (10)
- 5) List and explain the clinical data management activities in clinical trial. (10)

### SECTION - B

**Answer all the questions.**

Answer the following (5 marks x 5 = 25 marks)

- 6) Discuss the four pillars of ethics in clinical research. (5)
- 7) Describe the roles and responsibilities of contract research organization and clinical research associate. (5)
- 8) Explain the process of site/investigator selection for clinical trial. (5)
- 9) Explain the role and responsibilities of pharmacists in a clinical trial. (5)
- 10) Mention five reasons for fraud and misconduct in clinical research. State two impact of fraud and misconduct in clinical research. (5)

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