

# Question Paper

Exam Date & Time: 18-May-2023 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

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

**Clinical Research and Pharmacovigilance [PHA-MPL204T -S2]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Outline the components of investigator brochure (10)
- 2) A CRO wishes to conduct a clinical trial for an investigational test molecule in India. Assuming that all the necessary pre-clinical safety and efficacy tests are already conducted and are found satisfactory, explain how the CRO should obtain approval for the study (10)
- 3) Explain how subjects can be randomized into treatment groups where their baseline characteristics for gender, age, smoking status, economic status etc. are equally distributed among the treatment groups (10)
- 4) Discuss the historical milestones achieved in the progress of pharmacovigilance (10)
- 5) Describe the various study designs used in pharmacoepidemiology (10)

### SECTION - B

**Answer all the questions.**

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

- 6) List the principles of Belmont report and explain the relevance of each one in clinical trials (5)
- 7) Explain the responsibilities of ethics committees in clinical trials (5)
- 8) Write a short note on case report forms (5)
- 9) Explain the linkage between ADRs and drug prescription (5)
- 10) Describe the safety tests conducted to market a cardiovascular drug (5)

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