

Exam Date & Time: 13-Sep-2021 (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]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Describe the essential components of an informed consent form (10)
- 2) Explain the purpose of pharmacoepidemiology in a health care system (10)
- 3) Explain the different types of clinical research designs (10)
- 4) Describe the types of adverse drug reactions. Explain the detection and reporting methods to assess the ADRs (10)
- 5) Discuss International Classification of Diseases (10)

### SECTION - B

**Answer all the questions.**

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

- 6) List the composition of Institutional Ethics Committee (5)
- 7) Compare and contrast cohort and case control studies (5)
- 8) Provide a historical account for pharmacovigilance to emerge in the domain of safety pharmacology (5)
- 9) Write a short note on 'Essential Documents' required for conducting a clinical trial (5)
- 10) Differentiate between cost minimization and cost benefit analysis methods (5)

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