

Question Paper

Exam Date & Time: 21-May-2024 (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 -S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Describe the purpose, contents and regulatory considerations linked with an Investigator Brochure in clinical trial documentation (10)
- 2) Explain the roles and responsibilities of a principal Investigator and clinical research associate. (10)
- 3) Explain the method to randomize subjects when the patient characteristics vary significantly during the course of recruitment. (10)
- 4) Explain the key components of a pharmacovigilance system in ensuring the safety and efficacy of pharmaceutical products (10)
- 5) Describe the principles and methodologies used in pharmaco-economic evaluation (10)

SECTION - B

Answer all the questions.

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

- 6) List the principles of Belmont report. Explain their significance in the conduct of clinical trials. (5)
- 7) Discuss the various types of ADRs providing examples for each (5)
- 8) What is a cohort design in clinical research? Illustrate it. (5)
- 9) Explain the structure and coding system used in the International Classification of Diseases (5)
- 10) Evaluate the role of pharmacoepidemiology in clinical practice and healthcare policy (5)

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