

Exam Date & Time: 14-Mar-2022 (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]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain drug development process (10)
- 2) Discuss different types of study designs (10)
- 3) Discuss clinical trial start up activities (10)
- 4) Elaborate the process of "close out visit" (10)
- 5) Explain Clinical Trial data management (10)

SECTION - B

Answer all the questions.

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

- 6) Outline different randomisation technique (5)
- 7) Explain investigators brochure (5)
- 8) Discuss the preparation and maintenance "Trial Master file" (5)

- 9) Elaborate quality control and quality assurance in "Clinical Trial Data management" (5)
- 10) Outline different auditing of clinical trial document (5)

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