Question Paper

Exam Date & Time: 15-Apr-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

V Year Pharm D/ II Pharm D Post Baccalaureate
University Examination April 2024

Clinical Research [PPR 5.1T-S1]

Marks: 70 **Duration: 180 mins.**

A: Long Answer Questions

Answer all the questions.

Draw diagrams wherever necessary

1)	Explain the various phases of clinical trials	(10)
2)	Explain the principles of ICMR guidelines for clinical research	(10)
3)	List the tools and databases utilized in post marketing surveillance system and explain ANY two of them	(10)

B: Short Answer Questions

Answer all the questions.

4)	Define bioequivalence. Explain the process of abbreviated new drug application submission	(5)
5)	Discuss the review process by institutional ethics committee for different study designs	(5)
6)	State the roles and responsibility of clinical research associate in clinical research	(5)
7)	Explain the challenging of implementation of regulatory guidelines in India.	(5)
8)	Explain the history behind the establishment of Declaration of Helsinki	(5)
9)	Explain the advantages and disadvantages of electronic case report form.	(5)

C. Give Reasons for the Following

Answer all the questions.

10)	Health volunteers are also considered during drug discovery and development process	(2)
11)	Clinical trial should be carried out with certain essential documents	(2)
12)	Electronic data capturing system in clinical research eases data management	(2)
13)	Expedited approval of certain drugs approved by USFDA	(2)
14)	Safety of medicine is evaluated during clinical trial	(2)

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