Question Paper

Exam Date & Time: 10-Apr-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Answer ALL questions.

Clinical Research [PPR 5.1T-S2]

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

Section A

Answer all the questions.

Long Answer Questions (3 x 10 marks = 30 marks)

1)	Define investigational new drug application (IND). Explain the IND submission and processes	(10)
2)	Prepare a case report form (CRF) for a research protocol of myocardial infraction with dyslipidaemia as a comorbidity	(10)
3)	Describe periodical safety monitoring report in clinical research	(10)

Section B

Answer all the questions.

Short Answer Questions (6 x 5 marks = 30 marks)

4)	Discuss the advantages and disadvantages of Phase 4 in clinical trials	(5)
5)	Explain the duties of responsibilities of CDSCO	(5)
6)	Differentiate the roles and responsibilities of auditor and monitor in clinical research	(5)
7)	List the vulnerable populations and explain the informed consent process for pregnant women	(5)
8)	What are various dosage form in which a new drug can be developed?	(5)
9)	Explain the record keeping and archiving of clinical research/trial data	(5)

Section C

Answer all the questions.

Give Reasons for the Following (5 x 2 marks = 10 marks)

10)	Phase 2 clinical trial has two sections	(2)
11)	Waiver of consent from institutional ethical committee (IEC)	(2)
12)	The regulatory authorities realizing the importance of applying appropriate measures to stifle the increasing incidences of adverse reactions	(2)
13)	CTRI registration is required for clinical trials	(2)
14)	An abbreviated new drug application contains data which is submitted to FDA for the review	(2)

-----End-----