Question Paper

Exam Date & Time: 12-Jun-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Instructions: Answer ALL questions.

Clinical Research [PPR 5.1T-S3]

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

Section A

Answer all the questions.

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

1)	Once the drug is launched to the market, what are the possible methods to evaluate the benefits and risk of the drug?	(10)
2)	Explain the criteria for selection of institutional ethical committee members	(10)
3)	What are the various drug delivery systems concerning a drug molecule that can alter it pharmacokinetic property?	(10)

Section B

Answer all the questions.

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

4)	Is it possible to launch a generic drug into market by a new manufacturer? Why?	(5)
5)	Prepare a case report form for a research protocol (CRF) of diabetes mellitus with dyslipidaemia as a comorbidity	(5)
6)	State the roles and responsibility of investigator in clinical research	(5)
7)	Explain the conflict of interest with examples in a clinical trial	(5)
8)	Explain the ethical principle behind informed consent process according to Declaration of Helsinki	(5)
9)	Explain the requisites for informed consent process	(5)

Section C

Answer all the questions.

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

10)	Recruitment of participants to clinical trials are challenging in India	(2)
11)	India is making the progress in clinical research from last 5 years	(2)
12)	ORACLE CLINICAL is an important tool used in clinical research	(2)
13)	Informed consent process during emergency and disaster situations	(2)
14)	Patient information sheet also should be in the local language	(2)

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