

Your Roll Number

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Centre for Translational & Clinical Research
M.Sc. in Clinical Research Semester III
Semester Examination – December 2023

Paper Code – MCR-DCC 302; Paper Title: CONCEPTS IN CLINICAL TRIAL

Time : 2 hour 30 mins

Total Marks: 60

Write the roll number at the top immediately on receipt of this question paper. Attempt all questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples whenever necessary

Section-A	
All questions are compulsory	
	(10x2=20 Marks)
1	Trial bias
2	NOAEL
3	Sham surgery
4	Surrogate biomarkers
5	Blinding
6	LD50
7	HED
8	Dose Limiting Toxicity
9	Multiple ascending dose
10	PSUR
Section-B	
Write Short Note on ANY FOUR of the following	
	(4x5=20 Marks)
11	Cross over design
12	Placebo
13	Non inferiority Trials
14	Phase 0.
15	Trial design for antihypertensive drugs
16	Nocebo
Section-C	
Attempt TWO of the following	
	(2x10=20 Marks)
17	Discuss the points to be considered in designing of Phase I trials
18	What is the importance of biomarkers and write down about biomarker development?
19	Discuss the points considered for trial on geriatric population
20	What is the importance of screening. Discuss methods used and challenges ?

*****END OF QUESTION PAPER*****