Name: **Enrolment No:**	

UPES

End Semester Examination, December 2023

Course: Management of clinical trial **Semester: 3rd**

Program: Int. (B.Sc. M.Sc. Clinical Research) **Duration: 3 Hours**

Course Code: HSCR2015 **Max. Marks: 100**

Instructions: Attempt all questions, use flowcharts where required.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define Adverse drug reaction	1.5	CO1
Q 2	What is Adverse event?	1.5	CO1
Q 3	What do you mean by Good clinical Practice?	1.5	CO1
Q 4	Define Case report form.	1.5	CO1
Q 5	Differentiate audit certificate and audit report.	1.5	CO1
Q 6	Define the term impartial witness.	1.5	CO2
Q 7	Distinguish the term single and multicentric clinical trial?	1.5	CO2
Q 8	Describe the term Randomization.	1.5	CO2
Q 9	Differentiate observational and investigational clinical research.	1.5	CO2
Q 10	What is translational medicine?	1.5	CO2
Q 11	What is placebo?	1.5	CO3
Q 12	What are the regulatory authorities in clinical trial	1.5	CO3
Q 13	Differentiate the terms serious adverse drug reaction and serious adverse event.	1.5	CO3
Q 14	Who is the sponsor in clinical trials?	1.5	CO3
Q 15	What do you mean by subject identification code?	1.5	CO3
Q 16	Define institutional review board?	1.5	CO4
Q 17	What is special population in clinical trial?	1.5	CO4
Q 18	What is Independent Data Monitoring Committee.	1.5	CO4
Q 19	What do you mean by blinding/masking.	1.5	CO4
Q 20	Discuss the term coordinator.	1.5	CO4
	Section B **(4Qx5M=20 Marks)**		
Q 1	Explain the term micro dosing phase 0 trial. describe the significance of this phase in the drug discovery.	5	CO2

Q 2	Explain the responsibilities of CRA auditor	**5**	**CO2**
Q 3	Illustrate the term CRF, write the format and guidelines for filling the CRF.	**5**	**CO3**
Q 4	Outline the importance of surrogate biomarkers in clinical trials?	**5**	**CO3**
Section C (2Qx15M=30 Marks)			
Q 1	Discuss the History of clinical trial, and describe the new drug development process in detail, and write the need of drug development.	**5+5+5**	**CO4**
Q 2	What is the purpose of control group in clinical trial, types of controls in clinical trials, discuss the advantage and disadvantage of placebo control.	**5+5+5**	**CO4**
Section D (2Qx10M=20 Marks)			
Q 1	Define Micro-dosing or phase 0, and importance in relation to clinical research.	**5+5**	**CO3**
Q 2	Differentiate observational and interventional clinical trial design, discuss the strength and weakness	**5+5**	**CO4**