Name: **Enrolment No:**	

UPES

End Semester Examination, December- 2024

Course: Fundamentals of Clinical Research — **Semester: V**

Program: Integrated B.Sc., M.Sc.- Microbiology — **Duration: 3 Hours**

Course Code: HSCR30100 — **Max. Marks: 100**

Instructions: Read all the questions carefully.

S. No.	**Section A** **Short answer questions/ MCQ/T&F** **(20Qx1.5M= 30 Marks)**	**Marks**	**COs**
Q1.	Phase IV is also called as _____ a) Post marketing surveillance. b) First in man studies c) Efficacy and short-term safety d) Safety and efficacy profile in border term	1.5	CO1
Q2.	Preclinical studies involve evaluation of investigational new drug on healthy volunteers. State whether the statement is True or False.	1.5	CO1
Q3.	A _____ is a comprehensive description of a clinical trial's design, objectives, and methodology. a) Protocol b) Investigator brochure c) Informed consent d) Adverse drug reporting	1.5	CO1
Q4.	What does randomization in clinical trials help reduce? a) Cost b) Bias c) Time d) Complexity	1.5	CO1
Q5.	Crossover trials involve each participant receiving multiple interventions at different times. State whether the statement is True or False.	1.5	CO1
Q6.	In a placebo-controlled trial, the placebo is: a) The investigational drug b) A treatment with active ingredients	1.5	CO1

	c) A substance with no therapeutic effect d) A higher dose of the drug being tested		
Q7.	Which regulatory body oversees drug approvals in the United States? a) WHO b) FDA c) EMA d) NIH	1.5	CO1
Q8.	Phase IV clinical trials occur before the drug is approved for market use. State whether the statement is True or False.	1.5	CO1
Q9.	A double-blind study means: a) Only participants know the treatment assignment b) Only investigators know the treatment assignment c) Neither participants nor investigators know the treatment assignment d) Treatment assignment is not concealed at all	1.5	CO2
Q10.	Blinding in a trial eliminates all forms of bias. State whether the statement is True or False.	1.5	CO2
Q11.	The primary endpoint in a clinical trial is: a) The primary investigator b) The main result measured c) The number of participants d) The drug dosage	1.5	CO3
Q12.	Which phase focuses on testing in a small group for safety and dosage? a) Phase I b) Phase II c) Phase III d) Phase IV	1.5	CO3
Q13.	IEC stands for_____ a) Institutional Ethics Committee b) International Ethics Committee c) Independent Ethics Committee d) Indian Ethics Committee	1.5	CO3
Q14.	In schedule Y, Form_____is required for obtaining permission to conduct a clinical trial for a new drug in India a) Form 44 b) Form 21 c) Form 12 d) Form 13	1.5	CO3

Q15.	Which drugs come under the D&C act ? a) Adulterated Drugs b) Misbranded Drugs c) Spurious Drugs d) All of the above	1.5	CO3
Q16.	EMA stands for_____ a) European Medicine Agency b) European Medical Association c) European Marketing Agency d) European misbranding Agency	1.5	CO4
Q17.	ICH stands for _____. a) International Convention on Homogenization b) International Conference on Harmonization c) International Conference on Homogenization d) International Council on Harmonization	1.5	CO4
Q18.	Write full form of CDSCO.	1.5	CO4
Q19.	Define Schedule Y.	1.5	CO5
Q20.	In clinical trials, a washout period is: a) A time for analyzing results b) A time when participants switch treatments c) A period to remove effects of previous treatments d) When investigators take a break	1.5	CO5
	Section B **(4Qx5M=20 Marks)**		
		5	
Q1.	Distinguish between observational and experimental research design.	**5**	CO1
Q2.	What is the primary purpose of Phase I-IV clinical trials?	**5**	CO2
Q3.	Classify bias in clinical trials and methods to reduce bias in clinical research?	**5**	CO2
Q4.	Categorize different vulnerable populations and their consent process for clinical trial conduct.	**5**	CO3
	Section C **(2Qx15M=30 Marks)**		
		15	
Q1.	Discuss about the Phase IV post-marketing surveillance studies. Discuss the role of randomization and blinding in minimizing bias in clinical trials.	**(8+7)**	CO4

Q2.	***Case study:*** *In 2009, many people in the Maharaja Yashwantrao Public hospital were unknowingly enrolled in the clinical trial for Tonapofylline, a drug developed by Biogen Idec. Most of the patients were poor and illiterate and were informed that some charity was going to pay for their expensive treatments. Some of the patients in this trial suffered cardiac arrest and seizures.* **Question I.** Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no). **Question II.** What are the various types of ethical violations made in this trial?	(7.5+7.5)	CO4
Section D **(2Qx10M=20 Marks)**			
		10	
Q1.	Discuss in detail the stages of Drug Discovery and Development Process.	(6+4)	CO3
Q2.	Outline the objectives and provisions of the Drugs and Cosmetics Act, 1940, with respect to drug safety and efficacy.	(10)	CO5