Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

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.	**_____are the documents mandatory to enroll in a clinical research study.** a) Protocol b) Case Report Form c) Informed Consent Form d) Investigator's Brochure	1.5	CO1
Q2.	**A randomized design is_____** a) The subjects do not know which study treatment they receive b) Patients injected with placebo and active doses c) Randomly assigning subjects either for placebo or active dose d) Signed document of the recruited patient for the clinical trial procedures	1.5	CO1
Q3.	**How many people will be selected for phase II trial?** **a)** The whole market b) 300-3000 people c)20-300 people d) 20-50 people	1.5	CO1
Q4.	**A preparation that appears identical to the preparation of an active drug, but which has no biological activity?** a) Dummy drug b) Peptidomimetic c) Placebo d) Gazebo	1.5	CO1
Q5.	**The phase of trial is usually considered to start with the initiation of studies in which the primary objective is to explore therapeutic efficacy in patients?** **a)** Phase I b) Phase II c) Phase III d) Phase IV	1.5	CO1
Q6.	**Which one of the following definitions of the types of blinding used in clinical trials is INCORRECT?** a) Open label b) Single-blinded	1.5	CO1

	c) Double-blinded d) Triple-blinded		
Q7.	**A ---- endpoint has been defined as 'a biomarker intended to substitute for a clinical endpoint'** a) Soft b) Surrogate c) Hard d) Composite	1.5	CO1
Q8.	**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	CO1
Q9.	**Blinding in a trial eliminates all forms of bias**. State whether the statement is True or False.	1.5	CO2
Q10.	**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	CO2
Q11.	**IEC stands for_____** a) Institutional Ethics Committee b) International Ethics Committee c) Independent Ethics Committee d) Indian Ethics Committee	1.5	CO3
Q12.	**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
Q13.	**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
Q14.	**EMA stands for_____** a) European Medicine Agency b) European Medical Association c) European Marketing Agency d) European misbranding Agency	1.5	CO4
Q15.	**ICH stands for _____.** a) International Convention on Homogenization b) International Conference on Harmonization	1.5	CO4

	c) International Conference on Homogenization d) International Council on Harmonization		
Q16.	**Write full form of CDSCO.**	1.5	CO4
Q17.	**Define Schedule Y.**	1.5	CO5
Q18.	**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
Q19.	**ICMR was established in which year?** a) 1911 b) 1922 c) 1933 d) 1944	1.5	CO5
Q20.	**Drug and Cosmetics enacted in _____year** a) 1940 b) 1950 c) 1948 d) 1958	1.5	CO5
	Section B **(4Qx5M=20 Marks)**		
		5	
Q1.	Give an account on Preclinical testing and animal models.	(2+3)	CO1
Q2.	Classify bias in clinical trials and method to reduce bias in clinical research?	5	CO2
Q3.	Distinguish between observational and experimental research design.	(2+3)	CO2
Q4.	Discuss the different Clinical trial designs used in Clinical trials.	5	CO3
	Section C **(2Qx15M=30 Marks)**		
		15	
Q1.	***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.*	(7.5+7.5)	CO4

	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?		
Q2.	Elaborate the importance of Clinical trials along with objective, study group & size and timeline of different Phases of clinical trials.	(3+4+4+4)	CO4
Section D **(2Qx10M=20 Marks)**			
		10	
Q1.	Outline the objectives and provisions of the Drugs and Cosmetics Act, 1940, with respect to drug safety and efficacy.	(5+5)	CO5
Q2.	Discuss objecives of : 1) EMA 2) ICMR 3) Drug and Cosmetics Act 1940	(3+3+4)	CO5