Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Clinical Operations **Semester: III**

Program: B.Sc. Clinical Research **Duration: 3 Hours**

Course Code: HSCR2004 **Max. Marks: 100**

Instructions:

1. **This question paper consists of four sections.**
2. **All sections are compulsory.**
3. **Attempt all questions.**

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define the term "Action Letter" in the context of clinical trials.	**1.5**	**CO2**
Q2	Define the term "Case Report" in the context of clinical trials.	**1.5**	**CO2**
Q3	List **THREE** responsibilities of ethics committee.	**1.5**	**CO2**
Q4	List **THREE** categories of clinical trials based on the types of products being tested.	**1.5**	**CO2**
Q5	List **THREE** types of clinical trials based on observational design.	**1.5**	**CO2**
Q6	List **THREE** objectives of phase I of a clinical trial.	**1.5**	**CO2**
Q7	Differentiate phase 0 and phase I of clinical trials.	**1.5**	**CO2**
Q8	State **THREE** goals of phase 0 of clinical trials.	**1.5**	**CO2**
Q9	Define the term "blinding" in the context of clinical trials.	**1.5**	**CO2**
Q10	List **THREE** essential documents for the conduct of a clinical trial.	**1.5**	**CO3**
Q11	Explain the possible reasons for divergent results in phase II and phase III of clinical trials.	**1.5**	**CO5**
Q12	Differentiate between contract research organisation and site management organisation.	**1.5**	**CO1**
Q13	Outline the composition of ethics committee as per the ICMR national ethical guidelines for biomedical and health research involving human participants.	**1.5**	**CO3**

Q14	Define surrogate biomarkers.	**1.5**	**CO2**
Q15	Explain the term "Allocation Concealment" in context of clinical trial design.	**1.5**	**CO3**
Q16	List **THREE** classes of randomisation methods.	**1.5**	**CO3**
Q17	List **THREE** steps that can be used for guessing a sample size for a clinical trial.	**1.5**	**CO3**
Q18	Define the term "Detection Bias" in context of clinical trials.	**1.5**	**CO2**
Q19	Explain the role of allocation concealment in reducing performance bias.	**1.5**	**CO3**
Q20	List **THREE** important guidance documents regarding conduct of clinical trials in India.	**1.5**	**CO3**
Section B (4Qx5M=20 Marks)			
Q 1	Illustrate using a flowchart the steps to determine clinical doses for microdosing studies, based on the doses used in preclinical studies.	**5**	**CO1**
Q2	Summarize your understanding about the roles of FDA and sponsors in the conduct of clinical trials as well as in the clinical research enterprise in general.	**5**	**CO4**
Q3	Discuss randomisation in clinical trials as an approach to reduce bias and errors while emphasising on various types of randomisation methods.	**5**	**CO5**
Q4	Discuss the role of Phase IIb clinical trials in enhancing the efficiency of the clinical trials as whole.		**CO2**
Section C (2Qx15M=30 Marks)			
Q 1	Discuss in detail the **THREE** basic ethical principles mentioned in the Belmont Report.	**15**	**CO3**
Q2	Illustrate the timeline for biomarker discovery and evolution.	**15**	**CO2**
Section D (2Qx10M=20 Marks)			
Q 1	Outline the composition of ethics committee as per the ICMR national ethical guidelines for biomedical and health research involving human participants.	**10**	**CO3**
Q2	Discuss the information that is included in the package submitted for investigational new drug application.	**10**	**CO1**