

		(OR)			
	b)	Compare and contrast the strengths and weaknesses of randomized controlled trials (RCTs) versus cohort studies.	7+6	K1	CO1
12.	a)	Describe the Declaration of Helsinki, and why is it important in clinical trials?	6+7	K2	CO2
		(OR)			
	b)	Outline the ethical considerations surrounding the use of animals in clinical trials and the importance of the "3Rs" (Replacement, Reduction, and Refinement).	7+6	K2	CO2
13.	a)	Explain the purpose of Good Clinical Practice (GCP) guidelines and how they ensure the ethical conduct of clinical trials?	6+7	K3	CO3
		(OR)			
	b)	How does the Investigational New Drug (IND) application process work, and what are its key components?	7+6	K3	CO3
14.	a)	Elucidate the role of the Trial Master File (TMF) in clinical trial management and describe the essential documents that should be included.	8+5	K4	CO4
		(OR)			
	b)	How are electronic health records (EHRs) integrated into clinical trial data collection, and what advantages do they offer?	7+6	K4	CO4
15.	a)	Explain the concept of "intention-to-treat" (ITT) analysis in clinical trials and why it is considered the gold standard for handling dropouts and non-compliance.	8+5	K3	CO5
		(OR)			
	b)	Describe the role of the Data Monitoring Committee (DMC) in SAE reconciliation and explain how they contribute to maintaining trial safety and compliance.	7+6	K3	CO5

PART – C

(1 x 15 = 15 Marks)

Q.No.	Questions	Marks	KL	CO
16.	a) A pharmaceutical company is developing a new drug intended at treating a rare form of cancer. The company has completed pre-clinical studies, and the drug is now entering Phase I clinical trials to assess its safety, dosing, and pharmacokinetics in healthy volunteers.		K3	CO5

- i. Evaluate the design of a Phase I clinical trial for this new drug, focusing on the objectives, study population, dose escalation process, and safety monitoring mechanisms. 8
- ii. Discuss the role of pharmacokinetic studies in this phase and explain the steps required to progress to Phase II trials. 7

(OR)

- b) A researcher is designing a randomized controlled trial (RCT) to evaluate the efficacy of a new antidepressant compared to a placebo. The study will include 500 participants and last for 12 weeks. K3 CO5
 - i. Critically assess the design of the RCT, focusing on randomization, blinding, and control measures. 8
 - ii. Discuss the potential biases that may arise in the study and propose strategies to minimize them. 7