

- a) Both A and R are individually true and R is the correct explanation of A b) Both A and R are individually true but R is not the correct explanation of A
- c) A is true but R is false d) A is false but R is true
8. New drug not less effective by a predefined margin compared to control CO5 [K₂]
- a) Superiority trial b) Non inferiority trial
- c) Equivalence trial d) Inferiority trial
9. With two co-primary endpoints and a 5% significance level which of the following sets of results would lead to a significant primary end point. CO5 [K₃]
- 1) $p=0.026$, $p=0.030$
- 2) $p=0.049$, $p=0.051$
- 3) $p=0.00001$, $p=0.052$
- 4) $p=0.01$, $p=0.024$
- a) 1 only b) 3 and 4 only
- c) 1 and 4 only d) 4 only
10. The data management plan and study CRFs should be designed alongside: CO6 [K₂]
- a) The study handbook b) The investigators brochure
- c) The standard operating procedures d) Protocol

PART B (10 x 2 = 20 Marks)

11. What is a placebo and does placebo expire? CO1 [K₂]
12. What is the reason behind healthy volunteer (generally) in phase I clinical trial? CO1 [K₂]
13. Who are sponsors of clinical trial? Enumerate their role in clinical trial pre-IND meeting. CO2 [K₂]
14. What are the key responsibilities of Principal investigator? CO2 [K₂]
15. What are the benefits and risks of participating in a clinical trial? CO3 [K₂]
16. Define the role Sponsor in Investigator Brochure. CO4 [K₂]
17. What is annotated CRF? CO6 [K₂]
18. Assume the Human weight to be 50 kg and the Animal (Dog) dose is 10mg/kg. Calculate the HED (mg/kg). Calculate the maximum recommended starting dose (MRSD) assuming the safety factor to be 10. (Given: Conversion factor for Dog divide animal dose by 1.8 or multiply by 0.54). CO6 [K₃]
19. What is the minimum criterion required for a valid case in PV? CO6 [K₂]
20. Write a short note on Database lock in Clinical Data Management. CO6 [K₂]

PART C (6 x 5 = 30 Marks)

21. Write on the purpose of data monitoring committee (DMC). CO5 [K₂]
22. A professor working on cardiac function is hoping to develop a new drug candidate. He asks a colleague who works for industry to share some data from related work. The colleague is willing to share his data but asks that it be kept confidential and not shared with others. The data, when it arrives, is stamped "**confidential – Pre-IND**" and the request for confidentiality is repeated in a cover letter. The professor submits a grant application. During scientific review, a reviewer alleges that the preliminary work section of the application contains data that were obtained in another lab without that investigator's knowledge or permission. What is the principle violated? Comment on the ethics in the above case. CO2 [K₃]
23. List the roles of regulatory bodies in India for drug clinical trial process. CO4 [K₂]
24. Write the organizational structure of Institutional Ethical committee. CO5 [K₂]
25. Define Inclusion and Exclusion criteria in a clinical trial. CO6 [K₂]
26. Compare and contrast types of data entry in Clinical data management. CO6 [K₂]

Answer any FOUR Questions

PART D (4 x 10 = 40 Marks)

27. Elaborate the roles of international Ethical committee review guidelines that monitors the safety and efficacy of the vaccine clinical trial process. Draw a flow diagram of vaccine clinical trial process. CO1 [K₃]
28. Identify the major activities that occur during the drug development and approval process of a new antidiabetic drug. Comment on how toxicology models in Preclinical Research Studies translate to First in Human Studies. CO2 [K₃]
29. An investigation team has developed a thyroid drug and safety, and efficacy studies are completed in animals and humans. The thyroxine drug is to be tested in a tropical developing country with a poor health service system like Africa. Design a hypothetical cross-over design trial. CO5 [K₃]
30. Draw a schematic clinical trial CONSORT flow diagram for Factorial Design. Design an eligibility criterion, primary and secondary objective with a hypothetical example for a factorial clinical trial design. CO4 [K₃]
31. Describe in detail CTD modules in clinical trial according to ICH E6 Good Clinical Practice (GCP). CO6 [K₂]
