Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: Design of Clinical Trials, Conduct, Audit and Compliance — **Semester : 5**

Program: Integrated BSc – MSc Clinical Research — **Duration : 3 Hours**

Course Code: HSCR 3013 — **Max. Marks: 100**

Instructions: This question paper comprises of 4 sections.
Read the instructions before each section.
All questions are compulsory

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Which phase of clinical trials focuses on testing the drug's efficacy in a large group of patients? A. Phase I B. Phase II C. Phase III D. Phase IV	1.5	CO1
Q 2	Which of the following is a primary goal of randomization in clinical trials? A. To simplify data analysis B. To ensure patient compliance C. To minimize selection bias D. To reduce costs	1.5	CO2
Q 3	A study in which neither the participant nor the investigator knows the treatment assignment is called: A. Single-blind B. Double-blind C. Open-label D. Cross-over	1.5	CO3
Q 4	Which document outlines the procedure and goals for site audits in clinical trials? A. Case Report Form (CRF) B. Clinical Study Report (CSR) C. Audit Plan D. Informed Consent Form	1.5	CO4

Q 5	**In a cohort study, researchers typically:** **A. Compare two treatment options in the same group of patients** **B. Follow a group over time to observe outcomes** **C. Randomize subjects to treatment groups** **D. Collect data only at one point in time**	**1.5**	**CO1**
Q 6	**What is the primary focus of a bioequivalence (BE) study?** **A. To establish a drug's efficacy** **B. To ensure safety across populations** **C. To compare a generic drug to a branded drug** **D. To assess long-term side effects**	**1.5**	**CO1**
Q 7	**Which term describes trials that aim to prove a new treatment is not worse than the standard treatment by a specified margin?** **A. Superiority trial** **B. Non-inferiority trial** **C. Equivalence trial** **D. Observational trial**	**1.5**	**CO1**
Q 8	**In clinical trials, the use of a placebo aims to:** **A. Improve recruitment** **B. Eliminate side effects** **C. Minimize variability in results** **D. Increase compliance**	**1.5**	**CO3**
Q 9	**The main role of a Case Report Form (CRF) in a clinical trial is to:** **A. Summarize trial results** **B. Record all study-related data** **C. Inform patients of trial goals** **D. Monitor audit activities**	**1.5**	**CO1**
Q 10	**What type of study design would involve comparing a group of subjects with a condition to a group without it?** **A. Cross-sectional study** **B. Cohort study** **C. Case-control study** **D. Crossover trial**	**1.5**	**CO1**
Q 11	**A common method to measure compliance in clinical trials includes:** **A. Patient interviews** **B. Biomarker testing** **C. Randomization** **D. Placebo tracking**	**1.5**	**CO5**
Q 12	**Which of the following is not typically a characteristic of Phase IV trials?** **A. Long-term safety monitoring** **B. Real-world effectiveness assessment** **C. Initial dose determination** **D. Post-marketing surveillance**	**1.5**	**CO1**

Q 13	**In which clinical trial phase is the maximum tolerated dose often determined?** **A. Phase I** **B. Phase II** **C. Phase III** **D. Phase IV**	**1.5**	**CO1**
Q 14	**An audit that focuses specifically on adherence to the trial protocol is called_____** **A. Financial audit** **B. Regulatory audit** **C. Compliance audit** **D. Safety audit**	**1.5**	**CO4**
Q 15	**State the main purpose of stratification in clinical trials.**	**1.5**	**CO1**
Q 16	**List one method used to minimize variation in clinical trial results.**	**1.5**	**CO1**
Q 17	**Define an open-label study.**	**1.5**	**CO1**
Q 18	**List one advantage of using biomarkers in clinical trials.**	**1.5**	**CO1**
Q 19	**State the primary goal of Phase II trials.**	**1.5**	**CO1**
Q 20	**State the name of document that all participants must sign before joining a clinical trial.**	**1.5**	**CO1**
	Section B **(4Qx5M=20 Marks)**		
Q 1	**Explain the different types of randomization methods used in clinical trials. Discuss how each method helps minimize bias and improve the validity of the trial results.**	**(3+2)**	**CO2**
Q2	**Describe the key phases of clinical trials (Phase I-IV) and the primary objectives of each phase. Highlight the differences in design, sample size, and outcome measures across these phases.**	**(3+2)**	**CO1**
Q3	**Describe an audit plan in the context of clinical trials and explain why it is essential. Outline the main components of an audit plan, including the subject, timing, methods, and goals of the audit.**	**(3+2)**	**CO4**
Q4	**Discuss the significance of patient compliance in clinical trials. List the factors that can influence compliance and state the names of methods commonly used to measure and improve adherence in trials.**	**(3+2)**	**CO5**
	Section C **(2Qx15M=30 Marks)**		
Q 1	**A pharmaceutical company is designing a clinical trial for a new drug aimed at treating a chronic cardiovascular condition. Analyze and propose a comprehensive trial design covering the following aspects:**	**(3x5)**	**CO5**

	1. Type of study and justification (e.g., randomized, double-blind, etc.) 2. Selection criteria for participants, including inclusion and exclusion factors 3. Key randomization and blinding methods to reduce bias 4. Important endpoints and outcome measures 5. Strategies for managing and measuring compliance throughout the trial		
Q2	**Imagine you are part of an audit team assigned to conduct a compliance audit on a clinical trial site for an ongoing Phase III trial on a cancer medication. Develop a detailed audit plan that addresses the following components:** **1. Goals and objectives of the audit** **2. Key areas to be audited, including protocol adherence, documentation, and data integrity** **3. Methods for assessing patient compliance and protocol deviations** **4. Approach for reviewing informed consent processes and site SOPs** **5. Strategies for reporting findings and ensuring corrective actions are implemented**	**(3x5)**	**CO4**
Section D **(2Qx10M=20 Marks)**			
Q 1	**Describe in detail any FIVE important ethical considerations involved in conducting clinical trials.**	**(2x5)**	**CO2**
Q2	**Explain in detail the concept of blinding in clinical trials and discuss its importance in minimizing bias**	**(5+5)**	**CO3**