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	In which phase of clinical trials is long-term effectiveness and side effects typically assessed? A. Phase I B. Phase II C. Phase III D. Phase IV	1.5	CO1
Q 2	Which of the following best describes a crossover trial? A. Subjects are assigned randomly to treatment groups B. Subjects switch between treatments at a designated point C. Only one group receives a placebo D. It is conducted only in special populations	1.5	CO1
Q 3	A double-blind study minimizes which of the following? A. Cost of the trial B. Participant adherence C. Selection bias D. Observer and participant bias	1.5	CO3
Q 4	In a randomized controlled trial, stratification is mainly used to: A. Eliminate the need for a placebo B. Ensure balanced allocation of subgroups C. Increase the sample size D. Reduce trial costs	1.5	CO2
Q 5	What is a matched-pair study primarily used for in clinical trials? A. Comparing outcomes within individuals who receive different treatments	1.5	CO1

	B. Reducing costs associated with randomization **C. Reducing blinding requirements**		
Q 6	**The main focus of a Phase II clinical trial is to:** **A. Evaluate safety in healthy volunteers** **B. Determine optimal dosage** **C. Test long-term effectiveness** **D. Conduct post-marketing surveillance**	**1.5**	**CO1**
Q 7	**Which document provides a detailed description of the investigational product in a clinical trial?** **A. Informed Consent Form** **B. Case Report Form** **C. Investigator's Brochure** **D. Clinical Study Report**	**1.5**	**CO1**
Q 8	**In a clinical trial, what is the primary purpose of an Informed Consent Form?** **A. To record trial outcomes** **B. To outline the study objectives** **C. To ensure participant understanding and agreement** **D. To detail the trial methodology**	**1.5**	**CO1**
Q 9	**A non-inferiority trial is designed to:** **A. Test if a new treatment is less effective than a standard treatment** **B. Demonstrate that a new treatment is not worse than an existing one** **C. Confirm a drug's effectiveness across various populations** **D. Show that a new treatment is superior to existing treatments**	**1.5**	**CO1**
Q 10	**Which is NOT a typical component of a clinical trial audit?** **A. Monitoring participant recruitment** **B. Reviewing data quality and integrity** **C. Reviewing adherence to the protocol** **D. Conducting randomization**	**1.5**	**CO4**
Q 11	**A primary endpoint in a clinical trial refers to:** **A. The number of participants recruited** **B. The most important outcome measure** **C. The cost of the trial** **D. The secondary outcome measure**	**1.5**	**CO1**
Q 12	**What is a biomarker's role in clinical trials?** **A. Monitoring participant compliance** **B. Tracking budget expenditures** **C. Serving as an indicator for a disease or condition** **D. Conducting randomization**	**1.5**	**CO1**
Q 13	**An open-label study is most useful when:** **A. All participants need to receive a placebo**	**1.5**	**CO3**

	B. Blinding would be impossible due to treatment characteristics **C. The trial is in early phases** **D. The trial is highly complex**		
Q 14	**The main purpose of a Clinical Study Report (CSR) is to:** **A. Outline the study's final findings and results** **B. Record daily participant observations** **C. Act as an informed consent form** **D. Provide financial details of the trial**	**1.5**	**CO1**
Q 15	**State the main purpose of a non-inferiority trial.**	**1.5**	**CO1**
Q 16	**Define the concept of protocol compliance in clinical trials.**	**1.5**	**CO1**
Q 17	**List the primary purpose of a Phase I clinical trial.**	**1.5**	**CO1**
Q 18	**State the importance of patient compliance in clinical trials.**	**1.5**	**CO1**
Q 19	**List an important function of Institutional Review Board (IRB) in clinical trials.**	**1.5**	**CO1**
Q 20	**List one method commonly used for randomization in clinical trials.**	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
Q 1	**Explain the significance of inclusion and exclusion criteria in clinical trial design.**	**(2.5+2.5)**	**CO1**
Q2	**Differentiate between superiority, equivalence, and non-inferiority trials?**	**5**	**CO2**
Q3	**Discuss some common challenges in site auditing for clinical trials, and explain how these can be addressed?**	**(3+2)**	**CO4**
Q4	**Describe the purpose of a Case Report Form (CRF) and its role in clinical trials.**	**(3+2)**	**CO3**
	Section C **(2Qx15M=30 Marks)**		
Q 1	**A research team is planning a randomized controlled trial (RCT) to evaluate the effectiveness of a new drug for treating Type 2 diabetes. Design a trial framework that includes:** **1. The type of randomization to be used and its justification** **2. Blinding strategies, and potential challenges in implementing them** **3. Criteria for selecting participants, including inclusion and exclusion criteria** **4. Methods for measuring primary and secondary endpoints relevant to Type 2 diabetes** **5. Strategies for managing potential compliance issues with participants**	**(3x5)**	**CO5**

	Provide reasoning for each component, explaining how it contributes to the robustness and ethical integrity of the study.		
Q2	**You are tasked with conducting an audit of a Phase II clinical trial site that is testing an investigational drug for cancer treatment. Develop an audit checklist that includes:** **1. Key compliance areas such as informed consent, data integrity, and adherence to the protocol** **2. Specific documentation and records you would examine (e.g., case report forms, SOPs, participant medical records)** **3. Criteria for evaluating the quality and consistency of site operations** **4. Strategies for addressing any discrepancies or protocol deviations found during the audit** **5. Approaches for documenting and reporting audit findings to ensure transparency and corrective action** **Justify each item on your checklist, discussing how it supports the reliability and validity of the trial results.**	**(3x5)**	**CO4**
Section D **(2Qx10M=20 Marks)**			
Q 1	**Discuss any FIVE factors that impact participant recruitment and retention in clinical trials.**	**(2x5)**	**CO2**
Q2	**Explain any FIVE roles of standard operating procedures (SOPs) in ensuring compliance and consistency in clinical trials.**	**(2x5)**	**CO3**