Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: Fundamentals of Clinical Research **Semester : I**

Program: BSc Clinical Research **Duration : 3 Hours**

Course Code: HSCR1001 **Max. Marks: 100**

Instructions: Attempt all Sections

S. No.	Section A Short answer questions/ MCQ/T&F/One line answer (20Qx1.5M= 30 Marks)	Marks	COs
1	Which of the following best defines Clinical Research? A) A branch of healthcare science that determines the safety and efficacy of medications, devices, diagnostic products, and treatment regimens intended for human use. B) A type of research that only involves animal testing. C) A laboratory-based research focused solely on identifying new diseases. D) A type of theoretical research with no practical applications.	1.5	CO1
2	Which of the following term describes a study where neither the participants nor the researchers know who is receiving the treatment or placebo? A) Randomized B) Single-blind C) Double-blind D) Open-label	1.5	CO2
3	Which of the following is NOT a phase in clinical trials? A) Phase 0 B) Phase I C) Phase III b D) Phase V	1.5	CO3
4	In drug discovery, a "target" generally refers to: A) A disease symptom to be treated B) A protein or gene associated with a disease C) The final drug formulation D) A patient population	1.5	CO1
5	Which of the following regulatory body reviews and approves NDA Application in the United States? A) National Institute of Health (NIH) B) European Medicine Agency (EMA) C) Food and Drug Administration (FDA) D) Centre for Disease Control and Prevention (CDC)	1.5	CO2
6	Which of the following is a key ethical principle outlined in the Declaration of Helsinki?	1.5	CO3

	A) The welfare of animals in research B) The necessity of placebo controls in all trials C) Respect for human autonomy and the right to informed consent D) Full disclosure of commercial interests in clinical trials		
7	Which phase of clinical trials is conducted under an approved IND application? A) Preclinical trials B) Phase I, II, and III clinical trials C) Marketing analysis D) Post-marketing surveillance	**1.5**	**CO1**
8	Define "Clinical Research".	**1.5**	**CO2**
9	The European regulatory authority that evaluates and monitors medicinal products is the: A) FDA B) MHRA C) EMA D) WHO	**1.5**	**CO3**
10	Define "ICH E6 Regulation".	**1.5**	**CO1**
11	In target-based drug discovery, which type of molecules are typically targeted? A) Carbohydrates B) Proteins C) Lipids D) Vitamins	**1.5**	**CO2**
12	Define "Double Blinding" in clinical research.	**1.5**	**CO3**
13	Which of the following historical document laid the foundation for ethical principles in clinical research involving human subjects? A) The Helsinki Declaration B) The Nuremberg Code C) The Belmont Report D) The GCP Guidelines	**1.5**	**CO1**
14	Who is known as the "Father of Clinical Trials" for introducing the concept of control groups in research? A) Louis Pasteur B) Sir Ronald Fisher C) James Lind D) Hippocrates	**1.5**	**CO2**
15	Define "Investigational New Drugs".	**1.5**	**CO3**
16	What is NDA, and ANDA?	**1.5**	**CO1**
17	According to Good Clinical Practice (GCP), which of the following documents must be obtained from each clinical trial participant? A) Drug Interaction Report B) Informed Consent C) Adverse Event Report D) Investigator's Brochure	**1.5**	**CO2**
18	Define the term "Adverse Drug Reaction".	**1.5**	**CO3**
19	Which phase of clinical trials primarily assesses the efficacy of a drug?	**1.5**	**CO1**
20	The process of optimizing a lead compound for better activity, selectivity, and safety is called: A) Drug Repurposing B) Pharmacodynamics	**1.5**	**CO2**

	C) Lead Optimization D) High-throughput Screening		
Section B (4Qx5M=20 Marks)			
1	Explain the purpose and importance of obtaining informed consent from participants in clinical trials.	**5**	**CO1**
2	Discuss, why is the ethics committee's approval essential before a clinical trial can proceed.	**5**	**CO2**
3	Explain the purpose of the declaration of Helsinki in clinical research.	**5**	**CO3**
4	Discuss the role of James Lind in the development of clinical research, particularly regarding his work on scurvy. How did his findings contribute to the foundation of evidence-based medicine?	**5**	**CO2**
Section C (2Qx15M=30 Marks)			
1	A hospital is conducting a clinical trial to test a new vaccine for a viral infection that primarily affects children under the age of 5. The vaccine has passed Phase I trials, showing no significant adverse effects. The hospital plans to begin Phase II trials in a pediatric population. However, there are concerns regarding the safety of the vaccine in children, especially given that the viral infection does not pose a high risk to healthy children. The parents of the participants will be asked to provide consent for their children's involvement in the study. 1. What ethical concerns arise when testing a vaccine on children, especially when the viral infection is not life-threatening? (5 marks) 2. How should the Ethics Committee address these concerns when reviewing the trial protocol? (5 marks) 3. What factors should the Ethics Committee consider when conducting a risk-benefit analysis for this pediatric vaccine trial? What safeguards should be put in place to minimize potential harm to the children involved in the study? (5 marks)	**15**	**CO4**
2	A clinical trial is being conducted for a new drug intended to treat a rare genetic disorder that affects only a small population worldwide. Due to the rarity of the disease, only a limited number of patients qualify for the trial. The Ethics Committee reviews the trial protocol and raises concerns about the lack of long-term data on the drug's effects. The trial will be conducted as a single-arm study with no placebo control, and the potential for adverse events remains unclear. 1. What are the critical elements that should be included in the informed consent document for this clinical trial? (5 marks) 2. How can the research team ensure that participants' consent is informed and voluntary? (5 marks) 3. How can the clinical trial protocol ensure that participants' data is kept confidential and that their privacy is protected throughout the study? (5 marks)	**15**	**CO5**
Section D (2Qx10M=20 Marks)			
1	Mention the formula for sample size calculation in clinical research. If a researcher is conducting a study on the prevalence of a disease with an estimated prevalence of 20%, a	**10**	**CO4**

	confidence level of 95%, and a margin of error of 2%, calculate the sample size required for a population of 100,000 people. Show all the calculations. Or Describe the key stages involved in the drug discovery process, from target identification to preclinical testing. Highlight the importance of each stage in ensuring the development of an effective and safe drug.		
2	Explain the essential documentation required in clinical research and outline the regulatory prerequisites that must be met.	**10**	**CO5**