

Name:

Enrolment No:



UPES
End Semester Examination, December 2023

Course: Fundamentals of Clinical research
Program: Integrated B.Sc.+M.Sc. (Clinical Research)
Course Code: HSCR2013

Semester: III
Time : 03 hrs.
Max. Marks: 100

Instructions: Attempt all the questions

S.No	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
	Attempt all the questions		
Q1	How many days it might take for NDA approval? a) 15 days b) 30 days c) 60 days d) 6 months	1.5	CO1
Q2	The technique of randomization a) Creates masking b) Reduces biasness b) Manipulates the results d) All of the above	1.5	CO3
Q3	Which of the following phases of clinical trials is related to mainly pharmacokinetics? a) Phase 0 b) Phase 1 c) Phase 2 d) Phase 3	1.5	CO2
Q4	Which of the following studies are conducted in clinical studies? a) Efficacy b) Safety c) Pharmacodynamics d) All of the above	1.5	CO1
Q5	Target validation is about a) To find out a disease target b) To confirm a disease target c) To change a molecule d) To identify a molecule	1.5	CO1
Q6	Which of the following is a type of Information bias? a) Loss to follow-up bias b) Self-selection bias	1.5	CO3

	c) Misclassification bias d) Overdiagnosis bias		
Q7	Which of the followings type of study is mainly retrospective? a) Cohort b) Cross-sectional c) Case-control d) Case-series	1.5	CO3
Q8	Which of the followings is the most common study design? a) Parallel b) Cross-over c) Cluster d) Factorial	1.5	CO3
Q9	Belmont report principles are all except a) Justice b) Obedience c) Beneficence d) Consent	1.5	CO3
Q10	Which phase of clinical trial has the largest population?	1.5	CO5
Q11	Define Randomization.	1.5	CO3
Q12	Which are the two main components of ICH members?	1.5	CO3
Q13	Which guideline of ICH deals about stability?	1.5	CO4
Q14	What do you understand by teratogenicity?	1.5	CO4
Q15	What's your understanding about amendment in protocol?	1.5	CO3
Q16	What is the difference between adverse effect and adverse event?	1.5	CO2
Q17	What do you understand by schedule Y.	1.5	CO5
Q18	When is IND filed?	1.5	CO1
Q19	What is the meaning of justice in Belmont report?	1.5	CO4
Q20	What is the full form of US-FDA?	1.5	CO4

Section B
(4Qx5M=20 Marks)

Q1	Depict at least five characteristics of an ideal drug candidate.	5	CO1
Q2	What do you understand by prognostic and predictive biomarkers. Provide examples.	5	CO2
Q3	Analyze the significance of prospective and retrospective study with examples?	5	CO3
Q4	Evaluate the characteristics of Pharmacovigilance.	5	CO4

Section C
(2Qx15M=30 Marks)

(Case studies)

Q1	<p>Background: Chris was recruited to participate in a clinical trial by his oncologist, Dr. Blair. Chris has cancer, and the traditional treatments have been only intermittently successful. The clinical trial is a randomized, single-blinded, placebo-controlled study of a drug that may be beneficial to patients with the kind of cancer that Chris has. The trial is set to last one year, after which time enough data will have been accumulated to determine the efficacy of the new treatment. After six months in the study, Chris is not experiencing any signs of improvement, and he may in fact be getting worse. Dr. Blair continues to receive reports about the progress of the research subjects enrolled in both the treatment arm and in the placebo arm, and preliminary data seem to suggest that the drug is beneficial. During an examination, Chris asks Dr. Blair if he is in the treatment arm or the placebo arm. Chris requests that if he is in the placebo arm Dr. Blair switch him to the treatment arm, so that he can receive the possible benefits of the new treatment. Dr. Blair knows that Chris is in the placebo arm.</p> <p>Questions:</p> <ol style="list-style-type: none"> What single blind, randomized and placebo-controlled is meant to be here? Is it ethical to keep Chris in the placebo arm and should he be transferred to the treatment arm? What other options could be taken to not violate ethical guidelines? 	5+5+5=15	CO3
Q2	<p>Background:</p> <ul style="list-style-type: none"> The prevalence of prostate cancer has increased in your country over the last 5 years. You want to examine the association between calcium intake and prostate cancer risk. You have limited time and funding to conduct this study. <p>Questions:</p>	5+5+5=15	CO3

	<ul style="list-style-type: none"> a. What type of study would you conduct? b. Why would you conduct that specific type of study? c. What is the measure of association to calculate for this study? 		
Section D (2Qx10M=20 Marks)			
	Attempt all the questions		
Q1	What are your understandings about the objectives, goals and members of ICH. How it operates?	10	CO4
Q2	Describe and evaluate the drug discovery and developments process.	10	CO1