

Name:			
Enrolment No:			
<b>UPES</b> End Semester Examination, May 2023			
Course: Int BMSC CLINICAL RESEARCH-IV		Semester: IV	
Program: Perspectives in Clinical Evaluation			
Duration: 3 Hours			
Course Code: HSCR2019		Max. Marks: 100	
Instructions:			
<b>S. No.</b>	<b>Section A</b>	<b>Marks</b>	<b>Cos</b>
	<b>Short answer questions/ MCQ/T&amp;F</b> <b>(20Qx1.5M= 30 Marks)</b>		
<b>Q 1</b>			
1	What do you understand by PMCF?	1.5	CO4
2	What is a medical device?	1.5	CO1
3	What is Adhoc method of evaluation?	1.5	CO2
4	Which method of clinical evaluation is also known as Oxford quality scoring system?	1.5	CO2
5	Enlist any two clinical study databases.	1.5	CO1
6	What is Double blinded study?	1.5	CO1
7	Modified JADAD scoring system is based on three-point questionnaire. Is it true or false?	1.5	CO2
8	Define a placebo.	1.5	CO2
9	An implant is not a medical device. Is it true or false?	1.5	CO2
10	Define safety.	1.5	CO2
11	What do you understand by CONSORT?	1.5	CO2
12	Write full form of SaMD.	1.5	CO2
13	What do you understand by term withdrawl in clinical study?	1.5	CO1
14	Define a relative risk.	1.5	CO1
15	Define an adverse event.	1.5	CO3
16	What do you mean by cohort study of a medical device?	1.5	CO3
17	Enlist the significance of Phase II clinical study.	1.5	CO1
18	Give an example of external use medication that has been recalled from market.	1.5	CO3
19	What is a Randomised controlled trial Clinical investigation?	1.5	CO2
20	What is a clinical investigation plan?	1.5	CO4

**Section B**  
**(4Qx5M=20 Marks)**

Q 1			
1	What is a class I medical device?	5	CO3
2	Write a short note on Delphi score trial evaluation system.	5	CO2
3	Why is clinical evaluation important?	5	CO1
4	Differentiate between attrition bias and reporting bias in clinical trials.	5	CO4

**Section C**  
**(2Qx15M=30 Marks)**

Q 1			
1	How is clinical data assessed and analyzed. Explain in detail (write at least 800 words)?	7.5+7.5	CO3
2	Give detailed overview of Post Market Surveillance (write at least 800 words).	15	CO4

**Section D**  
**(2Qx10M=20 Marks)**

Q 1			
1	What are the different stages of clinical evaluation. Discuss in detail?	10	CO1
2	List out 8 questions involved in modified JADAD scoring system.	10	CO2