Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Perspectives in Clinical Evaluation **Semester: IV**
Program: Int BMSC Clinical Research **Duration: 3 Hours**
Course Code: HSCR2019 **Max. Marks: 100**

Instructions: Attempt all sections.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define stage 0 (zero) of clinical evaluation.	**1.5**	**CO1**
Q 2	Expand the abbreviation GSPRs.	**1.5**	**CO1**
Q 3	Stage 3 of clinical evaluation is 'Finalize the clinical evaluation report (CER)'. **True/False**	**1.5**	**CO1**
Q 4	The clinical evaluation must demonstrate the ……. and ……. of the device.	**1.5**	**CO1**
Q 5	Write the importance of CE marking.	**1.5**	**CO2**
Q 6	Mention the limitations of Ad Hoc methods for clinical trial evaluation.	**1.5**	**CO2**
Q 7	Jadad Score was developed by …….	**1.5**	**CO1**
Q 8	Define the term CONSORT.	**1.5**	**CO1**
Q 9	The clinical evaluation report is essential for obtaining …… marking for a device.	**1.5**	**CO1**
Q 10	Clinical evaluation report is prepared by …….	**1.5**	**CO1**
Q 11	Define post-market research.	**1.5**	**CO1**
Q 12	Post-market clinical follow-up is an optional component of the clinical evaluation process, which can be excluded if the pre-market data is adequate. **True/False**	**1.5**	**CO1**
Q 13	Define clinical equivalence.	**1.5**	**CO1**
Q 14	CONSORT is a set of guidelines for transparent and complete reporting of clinical trials. **True/False**	**1.5**	**CO1**
Q 15	State the challenges faced during post-market research.	**1.5**	**CO2**
Q 16	State the importance of stage 2 during CE marking process.	**1.5**	**CO2**
Q 17	PMCF is resource-intensive, requiring significant financial and human resources. **True/False**	**1.5**	**CO1**
Q 18	State the primary objective of post-market research.	**1.5**	**CO2**
Q 19	List the source of data that form part of CER.	**1.5**	**CO2**

Q 20	PMCF adds to the regulatory burden on medical device manufacturers. **True/False**	**1.5**	**CO1**
Section B **(4Qx5M=20 Marks)**			
Q 1	Elaborate the factors that should be considered while assessing the clinical data after clinical literature review.	**5**	**CO3**
Q 2	Discuss in detail 'Source of Literature' that should be searched during clinical evaluation.	**5**	**CO2**
Q 3	Describe the steps to evaluate the clinical trial plan of a novel glucometer by CONSORT method.	**5**	**CO2**
Q 4	Discuss in detail about PMCF study design.	**5**	**CO2**
Section C **(2Qx15M=30 Marks)**			
Q 1	Outline the relevant directives and guidance of post market clinical follow-up. (08 Marks) Differentiate post-market clinical follow-up from post-market surveillance. (07 Marks)	**15**	**CO3**
Q 2	**Case study:** A Medical device company has developed a novel neurostimulation device for chronic pain management. For clinical trial, the company has selected 100 volunteers and divided them between control and treatment group as per their birth date. Appropriate double blinding technique was used for the study. No data was maintained for the patients leaving the trial. a) Evaluate the above clinical trial by Jadad method. (5 marks) b) Calculate the score obtained by Jadad method for above clinical trial. (5 marks) c) Discuss the advantages and limitations of this method. (5 marks) OR a) Design the plan to evaluate a novel neurostimulation device for chronic pain management by Delphi method. (10 marks) b) Discuss the limitations of Delphi method. (5 marks)	**15**	**CO4**
Section D **(2Qx10M=20 Marks)**			
Q 1	Discuss the plan to assess and analyze the clinical data after literature search.	**10**	**CO3**
Q 2	Describe clinical evaluation report. Write in detail content of clinical evaluation report.	**10**	**CO3**