Register Number:……..

KUMARAGURU
college of technology
character is life

B.TECH DEGREE EXAMINATIONS: NOV/DEC 2022

(Regulation 2018)

Seventh Semester

BIOTECHNOLOGY

U18BTT7002: Preclinical and Clinical Regulatory Affairs

COURSE OUTCOMES

CO1: Understand the regulatory aspects and ethical considerations involving human subjects
CO2: Understand the timelines and resources required to discover and develop new drugs in a preclinical setting
CO3: Demonstrate an understanding of the critical features of each stage of the preclinical drug development process.
CO4: Classify different types of trial designs.
CO5: Apply and demonstrate critical analysis of clinical data using statistical analysis tools
CO6: Identify quality parameters of clinical research report.

Time: Three Hours **Maximum Marks: 100**

Answer all the Questions:-

PART A (10 x 2 = 20 Marks)

(Answer not more than 40 words)

1.	List down the documents required for approval of clinical trial process.	CO1	[K_2]
2.	Critically evaluate the three pillars of drug development process.	CO1	[K_5]
3.	What is an informed consent? What protections are there for participants in a clinical research study?	CO2	[K_2]
4.	What is a Human Equivalent dose? How do you convert animal dose to HED?	CO2	[K_4]
5.	What is blinding in clinical trials? What is its significance?	CO3	[K_5]
6.	Investigators wish to study the differences in patients with subtherapeutic concentrations of vancomycin via two different delivery systems. The results of this two-week study is reported below,	CO3	[K_2]

	Formulation A (n=55)	Formulation B (n= 62)
Subtherapeutic Vancomycin concentration	35	17

Calculate absolute risk reduction, odds formulation A & odds formulation B and NNT?

7.	When and why clinical trial database lock is performed?	CO4	[K_2]
8.	List down various types of clinical trials performed during new drug testing.	CO5	[K_4]
9.	What is placebo? List down its pros and cons.	CO5	[K_3]

10. List down the pros and cons of factorial design used in clinical trial process. CO6 [K_4]

Answer any FIVE Questions: -
PART B (5 x 16 = 80 Marks)
(Answer not more than 400 words)

11. a) Elaborate the process involved in randomized withdrawal design with clear schematic. 8 CO1 [K_2]

    b) List down the pros and cons of randomized withdrawal design. 8 CO1 [K_2]

12. a) Critically evaluate the process involved in Phase IV of clinical trials. 8 CO2 [K_4]

    b) Elaborate with neat sketch on Run-In and cross-over design of clinical trials 8 CO2 [K_2]

13. a) Elucidate on various steps involved in testing of hypothesis when performing clinical trials. 8 CO3 [K_2]

    b) What are the various prerequisite to be followed, when fixing the sample size. 8 CO4 [K_2]

14. a) What is Clinical Data management (CDM)? Enumerate various activities involved in CDM 8 CO5 [K_2]

    b) List down various tools used for CDM. 8 CO6 [K_2]

15. a) The dataset given below represent the time dependent changes in the blood glucose level before and after drug intervention. Interpret the datasets, perform the test of significance, report the p value and comment whether the drug intervention had any significant changes in the blood glucose level. 8 CO2 [K_4]

Time (min)	Blood Glucose level (Before drug Intervention)	Blood Glucose level (After drug Intervention)
0	130	100
30	150	90
60	90	90

    b) Elaborate on the concept of randomization in clinical trials and critically evaluate the merits and demerits of single and double blinding in clinical trials 8 CO3 [K_2]

16. a) The dataset below represents the time dependent changes in the OD values of bacterial cell culture after being treated with an unknown antibiotic. Interpret the datasets, perform the regression analysis, report the equation of the regression line, and comment on the r2 values for the datasets 8 CO3 [K_3]

Time (hr)	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5	5.5	6
OD	0.01	0.02	0.03	0.04	0.05	0.06	0.06	0.06	0.9	0.1	0.15	0.5

b) Elaborate the roles of regulatory bodies in India and list the roles of any two national and international regulatory agencies that monitors the safety and efficacy of the clinical trial process of a new drug. 8 CO4 [K_2]

****