KUMARAGURU college of technology
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M.TECH. DEGREE EXAMINATIONS: APRIL / MAY 2023

(Regulation 2018)

Second Semester

BIOTECHNOLOGY

P18BTE0006: Clinical Research and Management

COURSE OUTCOMES

CO1: Understand key areas of drug development, clinical research regulations, trial management.

CO2: Classify the roles and responsibilities of clinical research professions.

CO3: Develop skills in clinical research documentation.

CO4: Understand the general principles on ethical considerations involving human subjects.

CO5: Identify and classify different types Of trial designs.

CO6: Apply and demonstrate critical analysis skills using tools Of CDM.

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

Answer all the Questions:-

PART A (10 x 1 = 10 Marks)

1. Assertion (A): According to FDA, there are any differences between medical devices and drugs. CO1 [K_3]

   Reason (R): FDA does not differentiate between medical devices and drugs.

   a) Both A and R are Individually true and R is the correct explanation of A
   b) Both A and R are Individually true but R is not the correct explanation of A
   c) A is true but R is false
   d) A is false but R is true

2. A clinical trial is designed with the requirement that 500 evaluable subjects are required to achieve the correct level of power. If it was expected that 20 percent of subjects will be non-evaluable, how many subjects should you plan to recruit? CO1 [K3]

   a) 500
   b) 600
   c) 625
   d) 650

3. IMDRF stands for_____ CO2 [K_2]

   a) International Medical Device Regulators Forum
   b) Indian Medical Device Regulators Forum
   c) International Medical Device Regulators Facility
   d) Indian Medical Device Research Facility

4. CO2 [K_4]

Regulator body	Country
A. FDA	i. Australia
B. CMDCAS	ii.EU
C. MDD	iii. Canada
D. TGA	iv. USA

	A	B	C	D
a)	ii	iii	iv	i
b)	iii	ii	iv	i
c)	iv	iii	ii	i
d)	ii	iv	iii	i

5. Assertion (A): The null hypothesis in a superiority trial states that the two treatments are equal and the trial aims at rejecting the null hypothesis and proving that one treatment is better than the other by Δ CO3 [K_4]

Reason (R): In a superiority trial, upper limit of the confidence interval (CI) of the effect size of one intervention is above zero and crosses the upper bound margin Δ

a) Both A and R are Individually true and R is the correct explanation of A
b) Both A and R are Individually true but R is not the correct explanation of A
c) A is true, but R is false
d) A is false but R is true

6. Who is responsible for submitting the end of study report to the ethics committee? CO3 [K_3]

a) The investigator
b) The sponsor
c) The Regulatory Authority
d) The monitor

7. With two co-primary endpoints and a 5% significance level, which of the following sets of results would lead to a significant primary endpoint. CO4 [K_3]

1) p=0.026, p=0.030
2) p=0.049, p=0.051
3) p=0.00001, p=0.052
4) p=0.01,p=0.024

a) 1 only
b) 3 and 4 only
c) 1 and 4 only
d) 4 only

8. Assertion (A): The World Medical Association ethical guidelines were first formulated under the Declaration of Helsinki CO4 [K_2]

Reason (R): Declaration of Helsinki is not based on ethical guidelines

a) Both A and R are Individually true and R is the correct explanation of A
b) Both A and R are Individually true but R is not the correct explanation of A
c) A is true, but R is false
d) A is false, but R is true

9. What is the name of the UK based regulatory authority that recommended that the investigators recommence all immunization in their clinical trials subject to certain conditions? CO5 [K_2]

a) DCGI
b) RCGM
c) DSMB
d) AYUSH

10. According to ICH GCP when using electronic trial data handling and/or remote electronic trial data systems, the sponsor should ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data. This means keeping which of the following trails CO6 [K_3]

1. audit trail
2. data trail
3. edit trail

a) 1 only
b) 1 and 3 only
c) 1 and 2 only
d) 3 only

PART B (10 x 2 = 20 Marks)

11. 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, CO1 [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?

12. When and why clinical trial database lock is performed? CO1 [K_5]
13. List down various types of clinical trials performed during new drug testing. CO2 [K_1]
14. What is placebo? List down its pros and cons. CO3 [K_4]
15. List down the pros and cons of factorial design used in clinical trial process. CO3 [K_1]
16. List down the documents required for approval of clinical trial process. CO2 [K_1]
17. Critically evaluate the three pillars of drug development process. CO4 [K_5]
18. What is an informed consent? What protections are there for participants in a clinical research study? CO5 [K_4]
19. What is Human Equivalent dose? How do you convert animal dose to HED? CO5 [K_2]

20. What are blinding in clinical trials? What is its significance? CO6 [K_2]

PART C (10 x 5 = 50 Marks)

21. Elaborate the process involved in randomized withdrawal design with clear schematic. CO1 [K_2]
22. List down the pros and cons of randomized withdrawal design. CO1 [K_1]
23. Critically evaluate the process involved in Phase IV of clinical trials. CO2 [K_5]
24. Elaborate with neat sketch on Run-In and cross-over design of clinical trials. CO2 [K_2]
25. Elucidate on various steps involved in testing of hypothesis when performing clinical trials. CO3 [K_2]
26. List down various prerequisite to be following, when fixing the sample size. CO4 [K_1]
27. What is Clinical Data Management (CDM)? List various activities involved in CDM CO5 [K_2]
28. 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. CO5 [K_2]
29. Elucidate the roles and responsibilities of Contract Research Organization in performing clinical trials. CO6 [K_4]
30. Health Insurance Portability and Accountability Act (HIPAA) of 1996 is a United States Act of Congress enacted by the 104th United States Congress and signed into law by President Bill Clinton on August 21, 1996.
What is HIPAA act? List down the goals of HIPAA act. CO3 [K_5]

Answer any TWO Questions

PART D (2 x 10 = 20 Marks)

31. 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. CO1 [K_3]

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

32. Elaborate on the concept of randomization in clinical trials and critically evaluate the merits and demerits of single and double blinding in clinical trials CO3 [K_5]
33. 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 CO4 [K_4]

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

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