



Date: 17-04-2024

Dept. No.

Max. : 100 Marks

Time: 09:00 AM - 12:00 NOON

SECTION A - K1 (CO1)

Answer ALL the Questions		(10 x 1 = 10)
1.	Answer the following:	
a)	Define Relative Risk with an example.	
b)	What are the advantages of clinical trials?	
c)	What is the formula to determine sample size of one sample proportion?	
d)	Define censoring.	
e)	Define Exponential Distribution.	
2.	MCQ	
a)	In a case-control study of tuberculin skin-test reactivity within a bovine population in a certain region, what is the most appropriate measure of association between sex and reactivity? (i) Incidence Ratio (ii) Relative Risk (iii) Odds Ratio (iv) Attack Rate	
b)	Prevalence of disease is estimated from (i) Case control study (ii) Cross sectional study (iii) Cohort study (iv) Randomized trial	
c)	The non-parametric equivalent of an independent sample t-test is (i) Kruskal Wallis test (ii) Mann-Whitney U test (iii) Wilcoxon Signed Rank test (iv) Sign test	
d)	A study that begins with tests on animals is called as: (i) Preclinical study (ii) Phase I study (iii) Phase II study (iv) Phase III study	
e)	Which disease did Jonas Salk develop a vaccine for? (i) Cholera (ii) Polio (iii) Asthma (iv) Diabetes	

SECTION A - K2 (CO1)

Answer ALL the Questions		(10 x 1 = 10)
3.	Fill in the blanks	
a)	ICH stands for _____	
b)	The _____ model is commonly used in survival analysis to assess the effect of various factors on the time to an event.	
c)	The _____ is a non-parametric test used to compare the survival distributions of two or more groups.	
d)	The hazard function of Weibull distribution is _____	
e)	The _____ distribution is commonly used to model data where the hazard rate is not constant over time.	
4.	Match the following	
a)	Kaplan Meier PL method	- constant hazard rate
b)	Kruskal-Wallis Test	- used on paired nominal data
c)	McNemar test	- Hazard function increases initially
d)	Exponential distribution	- analogous to F-test
e)	Log normal distribution	- estimating the survival function

SECTION B - K3 (CO2)

Answer any TWO of the following **(2 x 10 = 20)**

5. Explain Mann-Whitney U test in detail. When do we prefer this test to t-test?

6.	What is the drug regulatory body in India? What are the responsibilities?
7.	State the pdf and derive the survival and hazard function of Gamma distribution.
8.	Explain Log rank test.

SECTION C – K4 (CO3)

Answer any TWO of the following (2 x 10 = 20)

9.	Discuss the various phases of clinical trials.
10.	The test performance for identifying certain health conditions based on MRI and Histology is given below:

MRI	Histology	
	Positive	Negative
Positive	58	4
Negative	12	24

Find the strength of agreement between MRI and Histology.

11.	Explain the following terms: (i) Hazard function (ii) Probability density function (iii) Survival function (iv) Cumulative Hazard function and state the relationship among these functions.
12.	Discuss the steps involved in Kaplan-Meier survival function.

SECTION D – K5 (CO4)

Answer any ONE of the following (1 x 20 = 20)

13.	From the following data find (a) Experimental event rate (b) Control event rate (c) Relative risk (d) Absolute risk reduction . Also interpret the results.									
	<table border="1"> <tr> <td></td> <td>Aspirin</td> <td>Placebo</td> </tr> <tr> <td>Microcardial Infarction fatal</td> <td>12</td> <td>28</td> </tr> <tr> <td>Microcardial Infarction Non-fatal</td> <td>131</td> <td>215</td> </tr> </table>		Aspirin	Placebo	Microcardial Infarction fatal	12	28	Microcardial Infarction Non-fatal	131	215
	Aspirin	Placebo								
Microcardial Infarction fatal	12	28								
Microcardial Infarction Non-fatal	131	215								

14.	(i) Give two reasons why the cox PH model is suitable for use in survival data analysis. (2 marks) (ii) Perform a statistical test to show that the interaction term is significant in the model. Take $\alpha=5\%$. (6 marks) (iii) Identify the baseline hazard for this model and state what it represents. (2 marks)
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SECTION E – K6 (CO5)

Answer any ONE of the following (1 x 20 = 20)

15.	(i) If T is continuous non-negative random variable having distribution function $F(t)$ and cumulative Hazard rate $R(t)$ then show that distribution of $R(t)$ is standard exponential. (5 marks) (ii) The Gamma distribution has a density function as, $f(x) = \frac{x^{\alpha-1} e^{-\frac{x}{\beta}}}{\beta^\alpha \Gamma \alpha}, x > 0.$ Let the parameter $\alpha=1$, Find the MLE of β based on complete sample. (5 marks) (iii) Discuss the procedure of Wilcoxon Signed Rank test for one sample. (10 marks)
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16.	The remission time (in weeks) for two groups of Leukaemia patients are given below: Group 1 : 6 6 6 7 10 13 16 22 23 6+ 9+ 10+ 11+ 17+ 19+ 20+ 25+ 32+ 32+ 34+ 35+ Group 2 : 1 1 2 2 3 4 4 5 5 8 8 8 8 11 11 12 12 15 17 22 23 Test the significant difference between the two treatments using log rank test.
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