INDIAN STATISTICAL INSTITUTE

Semestral Examination : Semester II (2024-25)

Course Name : ~~BSDA (~~M. Stat. 2nd year~~)~~ BSDA does not exist anymore!

Subject Name : Clinical Trials

Date: 28.04.2025 , Total marks: 60. Duration: 2 hrs. 30 min.
[You may answer as many questions as you wish. Maximum you can score is 50.]

1. Using a suitable urn-based allocation design (to be stated by you), prove that

$$\frac{a}{3a+b} + \frac{b}{3a+b}\cdot\frac{a+1}{3a+b+3} + \frac{b}{3a+b}\cdot\frac{b}{3a+b+3}\cdot\frac{a+2}{3a+b+6} + \frac{b}{3a+b}\cdot\frac{b}{3a+b+3}\cdot\frac{b}{3a+b+6}\cdot\frac{a+3}{3a+b+9} + \cdots = \frac{1}{3},$$

where $a, b > 0$. [10]

2. Suppose the primary question of a two-treament clinical trial is: "Did the patient die within 30 days of the procedure?" We want to design the trial to test the null hypothesis at the 5% significance level with 95% power. The trial wants to be able to detect a change in mortality rate from 20% to 5%. First, derive the required theory, and then find the required sample size. [6+3]

3. Consider a cyclic play-the-winner rule with three treatents, A, B, and C, having success probabilities 0.8, 0.6, and 0.4, respectively. Find the probability of a success for the 6th patient. [10]

4. The success probabilities of two treatments are p_A and p_B. Suppose the prior for (p_A, p_B) is such that (p_A, p_B) can take (a, c) with probability 1/3, (b, b) with probability 1/3, and (c, a) with probability 1/3, where $a < b < c$. If n_k patients are treated by treatment k and s_k successes and f_k failures are observed, $k = A, B$, define and obtain a suitable Bayesian adaptive allocation design for allocating the $(n+1)$st patient, where $n = n_A + n_B$. [10]

5. Consider a set up where interarrival times of the patients are exponentially distributed with mean α and the response times are exponentially distributed with mean β. Clearly mentioning all the assumptions, derive the probability of obtaining the response from the 4th patient before the entrance of the 14th patient. [10]

6. Discuss Gumbel model for a plase II trial. Also discuss how optimal safe dose can be obtained in a phase II trial for a general probability model. Write the expression to be maximized in a Cox model. [2+3+2=7]

7. In a vaccine trial, equal number of individuals are allocated to the vaccine group and the placebo group. After one month, a total number of infected is 96 and the vaccine efficacy is 80%. What would be the vaccine efficacy if the number of individuals in the vccine group were double the number in the placebo group?

[4]