M. SC. (APPLIED STATISTICS) (MSCAST)

Term-End Examination December, 2024

MST-019 : EPIDEMIOLOGY AND CLINICAL TRIALS

Time: 2 Hours Maximum Marks: 25

Note: (i) Question No. 1 is compulsory.

- (ii) Attempt any **two** questions from question numbers 2 to 4.
- (iii) Scientific calculator (non-programmable) is allowed.
- (iv) Symbols have their usual meanings.
- 1. (a) If the proportion of males in a study is 0.20 then find odds of males in the study.
 - (b) From the following options, select the most common purpose of randomisation. Also give the proper justification:
 - (A) To obviate the need of a placebo group.

- (B) To guard against ethical considerations.
- (C) To bypass blinding.
- (D) To achieve initial equivalence of the groups.
- (c) What is the meaning of term 'Equipoise' in clinical trials?
- 2. (a) Results of a study of 9000 participants with a follow-up period of 15-years and outcome of interest CHD are given as follows:

	Cases of	Person-times
	CHD	(in years)
Smokers	5800	40200
Non-smokers	3200	25500
Total	9000	65700

Give answers of the following questions:

- (i) What is the incidence rate of CHD among smokers?
- (ii) What is the incidence rate of CHD among non-smokers?
- (iii) What is the incidence rate of CHD among all participants?

- (b) In usual notations, we are given that $\delta = 0.06$, $\pi_1 = 0.70$, $\pi_2 = 0.82$, $\alpha = 0.05$ and $\beta = 0.20$. What will be the sample size?
- (c) Suppose regimen-A is considered equivalent to regimen-B if the difference in their efficacy is less than 5%. A trial on 80 patients on regimen-A revealed efficacy of 62% and on 120 patients on regimen-B revealed efficacy 65%. Can they be considered clinically equivalent at 5% level of significance?
- 3. For a cross-sectional study, explain each of the following in detail: 4+3+3
 - (i) Design of cross-sectional study
 - (ii) Analysis of data of cross-sectional study design
 - (iii) Advantages and disadvantages of crosssectional study design
- 4. In clinical trials there are various sources of bias. Explain any *twenty* of them.

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