No. of Printed Pages : 3

MST–019

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. 1

(b) From the following options, select the most common purpose of randomisation. Also give the proper justification : 2

(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

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 : 4

	Cases of CHD	**Person-times (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 ? 2

(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 ? 4

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 cross-sectional study design

4. In clinical trials there are various sources of bias. Explain any *twenty* of them. 10

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