SC

[1297]

SEAT No. _____ No of Printed pages: 03

SARDAR PATEL UNIVERSITY
M.Sc. (IV Semester) Examination
2018
Tuesday, 30th October
2 p.m. to 5 p.m.
STATISTICS COURSE No. PS04ESTA04
(Clinical Trials)

Note: Figures to the right indicate full marks of the questions. **(Total Marks: 70)**

1 Attempt all, write correct answers

i) Sample size does not depend upon which of the following
a) effect size
b) population variance
c) nature of blinding
d) study design

(ii) The survival times are which type of response?
a) continuous
b) time to event
c) binary
d) any of all

(iii) Which is the appropriate study design for the case: to compare aspirin and Sulfinpyrazone with placebo in a trial
a) factorial
b) group allocation
c) hybrid
d) historical control

(iv) What is the probability of selecting a block sequence allocating A:B in ratio 1:3
a) 1/2
b) 1/3
c) 1/4
d) 1/6

(v) Which of the following is not a group sequential test?
a) Pocock test
b) O'Brien-Fleming test
c) Gehan test
d) None of the above

(vi) What is odds ratio for a two arm study having,

Arm	Events	Sample
Intervention	2	10
Control	4	14

a) 1/4
b) 5/8
c) 8/5
d) 7/10

(vii) Which phase of clinical trial is a phase for market survellience?
(a) Phase I
(b) Phase III
(c) Phase II
(d) Phase IV

(viii) Which plot is used in identifying publication bias?
a) K-M Plot
b) Lebbe Plot
c) Forest Plot
d) Funnel Plot

(P.T.O.)

2 **Attempt ANY 7, each carries 2 marks**

(a) Describe one of the phase I designs.

(b) What are fixed allocation schemes? Describe one of them.

(c) Give main steps of CT protocol.

(d) What is the change in sample size 100 if the drop in rate is 0.1 and dropout rate is 0.2?

(e) Write down assumptions necessary for K-M method application.

(f) Describe the simplest phase I design.

(g) Define five terms related to meta analysis including I^2 statistic.

(h) What is efficiency of seperability of cross over design {AB, BA}?

(i) Define Cox proportional hazard model.

(j) What is special about exponential survival function?

3(a) Develop formula for estimating sample size for comparing two sample means.

3(b) State formula of sample size estimation in case of clinical trial for dichotomous response, and normal response. For the latter case, give a rough estimate of sample size if both population standard deviation and the effect to be detected are 1.

OR

3(b) A clinical trial is conducted to test the responses of two treatments including a control treatment, the response are continuous. Calculate the sample size required for testing treatment difference to be 0.0 against it being of magnitude 2.0 with type I probabilities of 5%, power to be 90% in cases when population sd is known to be 1.0. Comment on these size. *($\Phi^{-1}(.025) = -1.96$, $\Phi^{-1}(.10) = -1.282$)*

4(a) What is role of randomization scheme? Distinguish between simple and stratified randomization schemes.

4(b) Explain minimization method.

OR

4(b) Distinguish between parallel group design and cross over design.

5(a) Discuss the objectives of a meta analysis in clinical trials. Explain the role of odds ratio and risk ratio.

5(b) Compute risk ratio and its 95% CI for the following 4 studies. Write comment.

Sr no	Trial	Treatment	Control
1	DZP4	57/605	76/520
2	CFX2	126/856	185/978
3	PAG1	244/1680	70/406
4	PAH2	154/2563	218/1955

OR

5(b) Describe the difference between fixed effect model and random effect model in context of meta analysis.

6(a) Describe algorithm of Pocock's group sequential procedure.

6(b) In a problem of testing the null hypothesis of no treatment mean difference against the two sided alternative: treatment difference of ±1, the type I error was 5% and power was fixed at 90%. Population variance was 4.

If test of significance is to be repeated for 6 times as per Pocock's test, how many more participants would be required than a fixed sample size?
What is the sample size requirement if six interim analyses are planned as per O'Brien-Fleming test ?

($\Phi^{-1}(.025) = -1.96$, $\Phi^{-1}(.10) = -1.282$)

OR

6(b) What is survival clinical trial? What are its common objectives?
Given survival CT partial data compute survival probabilities filling the blank.

Patient No	Time	Censored	At risk	Event
1	30	No	20	1
2	50	Yes	19	1
3	55	Yes		0