SARDAR PATEL UNIVERSITY
M.Sc. (IV Semester) Examination /
Certificate Course in Biostatistics Examination
2019
Saturday, 30th March
2.00 p.m. to 5.00 p.m.
STATISTICS COURSE No. PS04ESTA24/PS04ESTA04
(Clinical Trials)

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

1   **Attempt all, write correct answers**   **08**

i)   For an equivalence trial sample size formula is a function of ___ constants.

     a) 2   b) 3

     c) 4   d) 5

(ii)   In two group response adaptive randomization, patient was given treatment A and was a success then the next patient would be given

     a) treatment A with probability 0.5   b) treatment B

     c) treatment A with higher allocation probability   d) treatment A

(iii)   A ____ % increase in survival is concluded if the Cox proportional hazard multiplicative form model coefficient is 0.93.

     a) 93   b) 7

     c) 0   d) 3

(iv)   What is the probability of selecting a block sequence allocating A:B in ratio 1:2?

     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) Wang-Tsaits test

(vi)   What are odds ratio and risk ratio respectively for a two arm study having, 2x2 table,

Arm	Events	Sample
Intervention	2	10
Control	4	14

     a) 7/10, 8/5   b) 5/8, 7/10

     c) 8/5, 7/10   d) 7/10, 5/8

(vii)   Alpha spending function is a term related to

     (a) Phase I and MTD   (b) Phase III and Interim analy

     (c) Phase II and sample size   (d) Phase IV survey

(viii) Funnel plot is used in test of _____
- a) Publication bias
- b) Betterment of Control over Intervention
- c) Proportional hazard
- d) Equivalence

2   **Attempt ANY 7, each carries 2 marks**   **14**

a) Describe 3 plus 3 design.

(b) What is the objective of adaptive allocation schemes?

(c) List common steps of a CT protocol.

(d) Develop quick formula of estimating sample size for normal response trial.

(e) Develop sample size formula in case of a SE trial.

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

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

(h) Define two descriptive statistics related to survival analysis.

(i) Write down assumptions necessary for application of Cox proportional hazard model.

(j) What is information fraction?

3(a) Develop formula for estimating sample size for comparing proportions in two independent sample case and paired sample case.   **06**

3(b) State formulas of sample size in case of clinical trial for normal response and time to event response. In context of normal response trial, what happens to the sample size estimate when population variance gets higher from 1 to 2 and the effect size increases from 0.5 to 1?   **06**

OR

3(b) Describe CRM.

4(a) Giving example, discuss the advantages and disadvantages of the three fixed allocation randomization schemes.   **06**

4(b) Explain minimization method and play the winner rule.   **06**

OR

4(b) Describe the objectives of cross over design and factorial design in design of a phase III clinical trial.

5(a) Discuss the objectives of a meta analysis in clinical trials. Distinguish between the fixed effect model and the random effect model.   **06**

5(b) Describe the purpose of forest plot. Given the following information make forest plot. Write your comment.   **06**

Sr no	Trial	Treatment	Control
1	DZP4	57/605	76/520
2	..	..	..
3	..	..	..
4	Overall	154/2563	218/1955

OR

5(b) Describe two alternative methods of comparing treatment groups in case of survival clinical trial.

6(a) What is bioequivalence trial? Develop any formula related to this trial. **06**

6(b) In a problem of testing the null hypothesis of no treatment mean difference **06** 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 5 times as per Pocock's test, how many more participants would be required than a fixed sample size?

$(\Phi^{-1}(.025) = -1.96, \ \Phi^{-1}(.10) = -1.282, \ C_p\,(5,.05) = 2.413, \ R_p(5, .05, .10) = 1.207)$

OR

6(b) What do you mean by group sequential test? Describe Pocock's group sequential procedure.

— X —

③

③