

**Post Graduate Diploma in Management (Hospital & Health Management)  
PGDM – 2021-23 Batch****Term – IV : Term End Examination**

<b>Course &amp; Code</b>	<b>: Clinical Epidemiology (HOM 717)</b>	<b>Reg. No.</b>	<b>:</b>
<b>Term &amp; Batch</b>	<b>: IV, 2021-23</b>	<b>Date</b>	<b>: 14/11/2022</b>
<b>Duration</b>	<b>: 3 Hrs</b>	<b>Max. Marks</b>	<b>: 70</b>

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**Instructions:**

- Budget your time as per the marks given for each question and write your answer accordingly.
  - Don't write anything on the Question Paper except writing your Registration No.
  - Mobile Phones are not allowed even for computations.
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**Part A:** Q. 1 to Q.10 (10 questions\*1 marks = 10 marks).

Q1. Which phas/e of a clinical trial is referred to as post-marketing surveillance?

- Phase 1
- Phase 2
- Phase 3
- Phase 4

Q2. Which of the following is INCORRECT in case of a clinical trial?

- All clinical trials must be blinded
- Randomization is a critically important step in a clinical trial
- All clinical trials must be approved by Institutional Ethics Committee before initiation
- It is mandatory to register clinical trials with Clinical Trials Registry of India

Q3. The purpose of a double-blinding in a clinical trial is to

- Achieve comparability of all arms of a clinical trial
- Avoid observer and participant bias
- Avoid confounding
- Avoid sampling variation

Q4. Variability in estimation due to unknown/uncontrollable factors

- Chance
- Bias
- Confounding
- Effect modification

Q5. Which of the following are guidelines for reporting clinical trials?

- a. STROBE
- b. SRQR
- c. CONSORT
- d. PRISMA

Q6. A randomized controlled trial always specifies a hypothesis

- a. True
- b. False

Q7. Which of the following types of random allocation ensures equal number of study participants in intervention and control arms?

- a. Simple randomization
- b. Block randomization
- c. Both
- d. None

Q8. BNP is a cardiac peptide which is elevated in patients with left ventricular (LV) dysfunction. If BNP level is used as a test for screening LV dysfunction, increasing the cut-off point of BNP levels will result in

- a. Increase in sensitivity
- b. Increase in specificity
- c. Increase in prevalence
- d. None of the above

Q9. Which of the following is NOT censored in survival analysis?

- a. Patients who die during the follow up period
- b. Patients who survive beyond the duration of follow up
- c. Patients who are lost to follow up
- d. Patients who withdraw from the study

Q10. Age is a prognostic factor for COVID-19 disease

- a. True
- b. False

**Part B:** Q.11 to Q.15 (4 questions \*5 Marks =20 Marks) Attempt any four.

Q11. What are the ways of expressing prognosis? Explain any two measures of prognosis in detail.

Q12. Explain the different types of randomization with examples. What is the advantage of block randomization over simple randomization?

Q13. Explain the terms 'blinding' and 'allocation concealment'. What is the difference?

Q14. What is lead time? Explain the concept of lead time bias.

Q15. What are nosocomial infections? What are the purposes of conducting surveillance of nosocomial infections?

**Part C:** Q.16 to Q.20 (4 questions \*10 Marks =40 Marks) Attempt any four.

Q16. List and explain the Bradford Hill's criteria for establishing causality.

Q17. Describe the phases of a clinical trial. Explain the purpose of each phase.

Q18. You have to evaluate a breast cancer screening and treatment programme which has been running in a tertiary care hospital since one year. Frame structure, process and output indicators that you will use to conduct the evaluation.

Q19. Write the differences between:

- i. Efficacy trial and effectiveness trial
- ii. Intention to treat analysis and per protocol analysis

Q20. A screening test with 95% sensitivity and 90% specificity is used in a population of 1000 people, of whom 10% are truly diseased. What is the probability of disease in a person who has tested positive using the screening test? If the prevalence of the disease increases to 20%, does the post-test probability change? If yes, how?

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