CD 01 & CD 02

I Semester Post Graduate Diploma in Clinical Research and Data Management Examination, July 2009
FUNDAMENTALS OF CLINICAL RESEARCH AND BASIC STATISTICS FOR CLINICAL RESEARCH

Time : 3 Hours   Max. Marks : 80

SECTION – A
(MCQ Type)

Each question carries **1** mark **only**.   (**1×10=10**)

1. Which one of the following is an observational study ?
   a) Open trial   b) Blind trial   c) Cohort study   d) None of them

2. The post marketing surveillance report should be submitted to the regulatory authorities _____ for the first two years after approval of the drug.
   a) every 6 months   b) every year   c) every two years   d) none of them

3. Which one of the following is the best study design ?
   a) Randomized controlled study
   b) Open trial
   c) Prospective cohort study

4. MAD study is conducted to assess
   a) Psychological disorder
   b) Mental ability (IQ test)
   c) Pharmacokinetic and pharmaco-dynamics of multiple doses of the drug

5. MTD is
   a) Maximum Toxic Dose   b) Minimum Toxic Dose
   c) Maximum Tolerable Dose   d) Minimum Tolerable Dose

6. The First Indian Pharmaceutical Company in India is _____.
   a) Hindustan Antibiotics Ltd.
   b) Bengal Chemicals and Pharmaceutical Works
   c) Dr. Reddy's Laboratories
   d) Ranbaxy Laboratories

P.T.O.

7. There are 52 cards in a pack. Each type (Diamond, Heart, Spade, Club) has 13 cards. What is the probability of getting a diamond from a pack of well-shuffled card ?

    a) 0.1   b) 0.25   c) 0.5   d) 1.0

8. In generic drug trial, which hypothesis will be of interest ?

    a) Hypothesis of superiority   b) Hypothesis of non-inferiority

    c) Hypothesis of equivalence   d) None of them

9. The Cmax values (ng/ml) of 15 subjects in a bio-availability study for molecule were recorded in ascending order as follows :

    4, 7, 7, 9, 10, 11, 13, 15, 15, 15, 17, 17, 19, 19, 20

    After calculating the mean, median and mode, an error is discovered : one of the 15's is really 17. The measures of central tendency which will change are :

    a) The mean only

    b) The mode only

    c) The median only

    d) the mean and mode

    e) All three measures

10. In a histogram, there will be _____ gaps between the bars.

    a) Small   b) Large   c) No

SECTION – B

Answer **any five** :   **(5×5=25)**

11. State briefly about the regulatory bodies that govern Pharma industry.

12. Enumerate the salient points of the patent process in India.

13. Give reasons why India is the preferred destination for the clinical research of most of the globally renowned Pharmaceutical Company.

14. What is protocol ? What are the contents of the protocol ?

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15. What is central limit theorem ?

16. The scatter plot is the basic graphical tool for investigating relationships between two continuous interval or ratio scaled variables – Explain.

17. Which are the different types of sampling methods ? What do you understand by "Sampling distribution" ?

18. An aeroplane is only allowed a gross passenger weight of 8000 kg. The weights of passengers travelling by air between Toronto and Vancouver have a mean of 78 kg and a standard deviation of 7 kg. What will be the approximate probability that the combined weight of 100 passengers will exceed 8,000 kg ?

SECTION – C

Answer **any three** : (10×3=30)

19. A sample of 30 people from one tribe has the individual heights as follows :

Sl. No.	Height (ft)	Sl. No.	Height (ft)	Sl. No.	Height (ft)
1	4.3	11	4.1	21	4.2
2	4.8	12	4.5	22	4.6
3	4.1	13	4.6	23	4.9
4	4.3	14	4.4	24	4.7
5	4.5	15	4.9	25	4.5
6	4.6	16	4.6	26	4.6
7	4.4	17	4.2	27	4.4
8	4.5	18	4.5	28	4.9
9	4.2	19	4.1	29	4.2
10	4.8	20	4.7	30	4.1

What is the standard height of that tribe ? Calculate 99% of the error of margin.

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20. Calculate cumulative frequency, relative frequency and percentage frequency for the following data.

Measurements	No. of Obj.
0.0-1.0	3
1.0-2.0	4
2.0-3.0	4
3.0-4.0	7
4.0-5.0	6
5.0-6.0	5
6.0-7.0	5
7.0-8.0	1
8.0-9.0	2
9.0-10.0	3

21. a) There are 10 influenza patients who will be subjected to a new drug. If the success rate of the drug is 0.8 and it follows a binomial distribution, calculate the probability that exactly 7 patients will be recovered by the drug.

   b) In a health survey of 55 schoolboys, it was found that the mean hemoglobin level was 10.2g per 100 ml with a standard deviation of 2.1. Estimate the mean hemoglobin level of the population of such schoolboys.

22. What is CRF ? Discuss the different issues involved in producing high quality CRF.

23. What is Pre-clinical study ? Describe the different types of pre-clinical studies.

24. What is meant by 'Generic Drug" ? What are 'Bioavailability' and 'Bioequivalence' ? Explain why BA/BE study is required ? Discuss various methods to compare the bioequivalence of the given drug.

SECTION – D

Compulsory : (15×1=15)

25. a) What is 'Clinical Trial' ? Explain the various phases of 'Clinical Trial'. Bring out the differences in phases of clinical trials. (1+7+2=10)

   b) What is Post Marketing Surveillance ? What are the advantages of PMS study ? **5**

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