Reg. No. : | | | | | | | | | | | | |

**Question Paper Code: U8C64**

B.E./B.Tech. DEGREE EXAMINATION, NOV 2024

One Credit

Biotechnology

21UBT864 INTRODUCTION TO STATISTICAL ANALYSIS SOFTWARE

(Regulations 2021)

Duration: 1.30 hours Maximum: 50 Marks

Answer All Questions

PART A - (9 x 2 = 18 Marks)

| | | | |
|---|---|---|---|
| 1. | What are the four phases of clinical trials, and list the primary objective of each phase? | CO1 U | |
| 2. | Define a clinical trial protocol. | CO1 U | |
| 3. | What is the role of an Institutional Review Board (IRB) in clinical trials? | CO1 U | |
| 4. | Mention the concept of a placebo and its role in clinical trials. | CO1 U | |
| 5. | Define a double-blind study in the context of clinical trials. | CO1 U | |
| 6. | Enlist the purpose of Clinical Data Management (CDM) in the clinical trial process. | CO1 U | |
| 7. | What is Clinical SAS and how is it used in the pharmaceutical industry? | CO1 U | |
| 8. | Name two key features of SAS that make it useful for clinical data management. | CO1 U | |
| 9. | What is the significance of CDISC standards in Clinical SAS programming? | CO1 U | |

PART – B (2 x 16= 32 Marks)

| | | | | |
|---|---|---|---|---|
| 10. | (a) | Demonstrate the key procedures used in Clinical SAS for data manipulation and reporting. Discuss PROC SORT, PROC REPORT, PROC FREQ, and PROC MEANS with examples related to clinical data. | CO1 U | (16) |
| | | Or | | |
| | (b) | Explain the different phases of clinical trials (Phase I-IV). Discuss the objectives, methodologies, and types of participants involved in each phase, and how they contribute to the development of a new drug | CO1 U | (16) |

11. (a) Create a SAS dataset called patients with the following columns and data:

| Patient_ID | Name | Age | Gender | Diagnosis |
|---|---|---|---|---|
| 101 | John | 45 | Male | Hypertension |
| 102 | Sarah | 50 | Female | Diabetes |
| 103 | Mike | 35 | Male | Asthma |
| 104 | Anna | 60 | Female | Hypertension |
| 105 | Alex | 55 | Male | Cardiovascular |

CO2 App (16)

- Write a SAS program to create this dataset.
- Write a SAS program to filter and display the details of patients who are older than 50 years.
- Write a SAS program to filter and display only the female patients diagnosed with either "Diabetes"

Or

(b) Write a SAS program to perform the following tasks:
Create a Dataset:

- Create a dataset called clinical_data with the following columns and sample data:

| Patient_ID | Age | Weight | Gender |
|---|---|---|---|
| 001 | 30 | 150 | Male |
| 002 | 45 | 180 | Female |
| 003 | 29 | 145 | Male |
| 004 | 60 | 200 | Female |
| 005 | 50 | 175 | Male |
| 006 | 37 | 160 | Female |
| 007 | 42 | 170 | Male |
| 008 | 54 | 185 | Female |
| 009 | 33 | 155 | Male |
| 010 | 48 | 165 | Female |

CO2 App (16)

- Generate a Histogram:
  - Using the clinical_data dataset, create a histogram for the Age variable.
  - Ensure the histogram has labeled axes: the x-axis should be labeled "Age of Patients" and the y-axis should be labeled "Number of Patients".
  - Add a title to the histogram that reads "Age Distribution of Patients".
- Print the Dataset:
  - Print the entire clinical_data dataset to display all columns and rows.