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Question Paper Code:R8C64

B.E./B.Tech. DEGREE EXAMINATION, NOV 2025

One Credit Course

R21UBT864 – INTRODUCTION TO STATISTICAL ANALYSIS SYSTEM

Biotechnology

(Regulations R2021)

Duration: 1.30 Hours

Maximum: 50 Marks

Answer ALL Questions

PART A - (9 x 2 = 18 Marks)

1. Define a clinical trial protocol. CO1-U
2. What is the significance of CDISC standards in Clinical SAS programming? CO1-U
3. What is the purpose of LIBNAME in SAS programming? CO1-U
4. What is Clinical SAS and how is it used in the pharmaceutical industry? CO1-U
5. Define SDTM (Study Data Tabulation Model) in the context of Clinical SAS. CO1-U
6. Mention the concept of a placebo and its role in clinical trials. CO1-U
7. Differentiate DATA step and PROC step in SAS. CO1-U
8. Mention the role of PROC SORT in organizing clinical datasets. CO1-U
9. What are CRF (Case Report Forms) and how are they related to SAS data management? 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) Write a SAS program to perform the following tasks:

CO1-App (16)

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

▪ 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.

Or

- (b) A clinical researcher is studying the systolic blood pressure (SBP) of patients diagnosed with hypertension. The researcher collects the following SBP readings (in mmHg) from 12 patients during a routine check-up:

CO1-App (16)

Patient_ID	SBP
1	140
2	145
3	130
4	140
5	155
6	150
7	160
8	145
9	135
10	140