AJEENKYA
D Y PATIL UNIVERSITY

End Term Examination (December 2019)

School: SOM **Program:** MSc CLINICAL RESEARCH

Course: CLINICAL TRIAL AND DATA MANAGEMENT **Course Code**: MGT684

Semester: 3rd **Max Marks:** 50 marks **Duration (mins):** 150 mins

Instructions to the students

1) *The Question paper consists of two sections- Section I and Section II.*
2) *All questions are compulsory.*
3) *Neat flow charts or diagrams must be drawn wherever necessary*
4) *Figures on the right indicate full marks*

SECTION 1

Q 1) Answer the following**:** **[2x5=10]**

a) Explain the meaning of project in clinical trial process.
b) What are the characteristics of project management?
c) Describe in brief adaptive studies.
d) Describe – Review of ambulatory or hospital medical records.
e) What are the various methods for collection of data from secondary sources?

Q 2) Attempt any two of the following: **[5x2=10]**

a) Explain the phases of clinical trials in detail.
b) What are the advantages and disadvantages of secondary data?
c) What are the roles and responsibilities of a project manager?
d) Explain in detail various methods used for collection of primary data.

Q 3) Attempt any one of the following**:** **[5x1=5]**

a) Describe in detail the recruitment and retention of study subjects in clinical trial process.
b) Explain the various stages involved in project management.

SECTION II

Q 1) Answer the following**:** **[2x5=10]**

a) What is EMA?
b) Describe the meaning of manual query writing.
c) Describe participants as key stakeholders in clinical trial process.
d) Elaborate CRC.
e) Explain confidentiality in clinical trial process.

Q 2) Attempt any two of the following: **[5x2=10]**

a) Explain in detail Clinical Trial Agreement (CTA) Process.
b) What are the roles and responsibilities of clinical research associate (CRA).
c) Describe in detail about the key stakeholders involved in clinical trial process
d) Differentiate between CRO and SMO.

Q 3) Attempt any one of the following**:** **[5x1=5]**

a) Describe Investigator's outlined in Good Clinical Practices and regulations.

b) Explain in detail logistics management organization in clinical research.

******* ALL THE BEST *******