



AJEENKYA

D Y PATIL UNIVERSITY

End Term Examinations (December 2018)

School: School Of Management -ICRI

Program: M.Sc.Clinical Research

Course: Site Management Organization

Course Code: MGT551

Semester: Semester I

Max Marks: 50

Duration (mins): 2 Hrs. (120 mins)

Note: 1. Figures to the right indicates full marks.

Q.1 Who is a sponsor? Enumerate Sponsor's responsibilities (10)

OR

Q.1 Explain in detail the role and responsibilities of sponsor in total quality control management system in clinical trial project. (10)

Attempt any four from the following

Q.2 Explain in detail site management services and the role and responsibilities of Clinical research Coordinator (CRC) (10)

Q.3 Explain the concept of risk based monitoring in Clinical research. (10)

Q.4 Explain in detail Clinical Trial Master File & Documents Management (10)

Q.5 Define Audit & Inspection. Explain provision of trial master file for inspection (10)

Q.6 Define an adverse event with adverse event management principals. Explain the different stages of adverse event management (10)

Q.7 Write a short note on (10)

Investigator's perspective on any two

- a. Selecting investigators and monitors
- b. Subjects Recruitment Process
- c. Subjects Retention & Study Compliance Management