



# AJEENKYA

## D Y PATIL UNIVERSITY

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### End Term Examination (December 2019)

**School:** SOM

**Program:** MSc Clinical Research

**Course:** Site Management Organization

**Course Code:** MGT551

**Semester:** I

**Max Marks:** 50

**Duration:** 2.5 hours

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Answer all of the following (2 marks each)

- 1) Define Clinical Research Organization
- 2) Explain Risk based Monitoring
- 3) Explain Feasibility Analysis
- 4) How is Resource Management done
- 5) What is difference between Clinical Trial Agreement and a Contract
- 6) Explain Project Initiation/start-up
- 7) Define Site Management Organization
- 8) Explain Trial site audits and inspections
- 9) Explain Vendor Selection process
- 10) List the documents in Dossier Management
- 11) Explain Supply chain and logistics management
- 12) What are Investigator's Obligation
- 13) Enlist the Monitor's responsibilities
- 14) Explain difference between SMO and CRO
- 15) Define Adverse Event Management
- 16) What is difference between audit and inspection
- 17) How is Subject Retention done
- 18) Explain subject recruitment process
- 19) How is Project Budgeting done
- 20) What are investigator's responsibility
- 21) Explain process of SMO selection
- 22) What does Lifecycle management mean
- 23) Explain Compliance management
- 24) How is study closeout done
- 25) Explain process of CRO selection

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