

School of Biomedical Science

Department of Biomedical Science

Mid Term Examination

Exam Date: 03 Oct 2023

Time : 90 Minutes

Marks : 50

Sem III - MBACRT3009 - Management Of Clinical Research Project and Outsourcing

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

- 1) What do you mean by Outsourcing? Explore the advantages of outsourcing. K2 (2)
- 2) Discuss briefly the project management life cycle. K1 (3)
- 3) Appraise the advantage and limitations of forecasting. K2 (4)
- 4) Illustrate the purpose of clinical trial monitoring? K2 (6)
- 5) Analyze the importance of routine and for-cause Audit? Describe the audit process in detail. K3 (6)
- 6) Distinguish between the clinical trial audit and Inspection? K3 (9)
- 7) Discuss the importance of budgeting clinical trial K4 (8)
- 8) Analyse the process of Dossier submission in regulatory affairs K4 (12)

OR

Analyse what is common technical document. Describe the requirements for compiling technical documents of a medical product as per ICH. K4 (12)