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School of Biomedical Science

**Bachelor of Science Honours in Healthcare and Clinical Research
Mid Term Examination - Nov 2023**

**Duration : 90 Minutes
Max Marks : 50**

Sem I - Q1UE101T - Introduction to Clinical researchGeneral Instructions

Answer to the specific question asked

Draw neat, labelled diagrams wherever necessary

Approved data hand books are allowed subject to verification by the Invigilator

- 1) What do you mean by Outsourcing? K2 (2)
- 2) Discuss briefly the phase I clinical trial K1 (3)
- 3) Appraise the scope of clinical research K2 (4)
- 4) Discuss the Informed consent process. K2 (6)
- 5) What is copyright. What is role of IP in pharma business K3 (6)
- 6) Distinguish between phase I and Phase II clinical Trial. K3 (9)
- 7) Describe briefly the need and scope of ICH guidelines K4 (8)

- 8) Analyze the importance of routine and for-cause Audit? Describe the audit process in detail. K4 (12)

OR

What is post marketing surveillance. Discuss the scope of Post marketing surveillance or phase 4 clinical trial. K4 (12)