

1.	Title of the course	Biostatistics
2.	Course number	MA616L
3.	Structure of credits	3-0-0-3
4.	Offered to	PG
5.	New course/modification to	Modification To MA6036/12
6.	To be offered by	Department of Mathematics and Statistics
7.	To take effect from	January 2022
8.	Prerequisite	CoT
9.	Course Objective(s): To introduce an overview of statistical methodologies with applications to dose response studies. To bestow statistical theory and methods of developing designs and models for analysing data in clinical trials. To discuss different objectives, phases, and methods of sample size determination in clinical research.	
10.	Course Content: Introduction: clinical trials, process, investigation, application, practice; Statistical concept: probability, interaction, inference, testing, significance; Randomization: models, methods, implementations, blinding; Designs: group designs, randomized designs, crossover designs, titration designs, up and down phase I designs, continual reassessment method phase I designs, multiple stage designs, randomized phase II designs; Classifications: multicenter trials, dose-response trials, combination trials, bridging studies and global trials, vaccine clinical trials; Analysis: estimation, hypothesis testing, ANOVA, ANCOVA, nonparametric methods; Sample size determination: basic concept, two samples, multiple samples; Analysis of categorical outcomes: independence, odds ratio, relative risk, logistic and multiple regression models.	
11.	Textbook(s): 1. Chow S C and Liu J P, <i>Design and Analysis of Clinical Trials - Concepts & Methodologies</i> , 3rd Edition, John Wiley & Sons (2013).	
12.	Reference(s): 1. Chow S C and Liu J P, <i>Design and Analysis of Bioavailability and Bioequivalence Studies</i> , 3rd Edition, Chapman and Hall (2008). 2. Chow S C, Shao J, Wang H and Lokhnygina Y, <i>Sample Size Calculations in Clinical Research</i> , 3rd Edition, Chapman and Hall (2017). 3. Daniel W W and Cross C L, <i>Biostatistics: A Foundation for Analysis in the Health Sciences</i> , 10th Edition, John Wiley (2013). 4. Friedman L M, Furberg C D, DeMets D L, Reboussin D M and Granger C B, <i>Fundamentals of Clinical Trials</i> , 5th Edition, Springer (2015).	