

PROFORMA FOR NEW COURSE

1.	Title of the Course	Biostatistics
2.	Course Number	MA6036
3.	Status of the Course	Elective
4.	Structure of Credits	3-0-0-3
5.	Offered To	PG
6.	New Course/Modification to	New
7.	To be Offered by	Department of Mathematics and Statistics
8.	To take effect from	January 2021
9.	Prerequisite	CoT
10.	Whether approved by the Department	Yes
11.	Course Objective: 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.	
12.	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.	
13.	Text book(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).	
14.	Reference(s): 1. Chow S C, Shao J, Wang H and Lohknygina Y, <i>Sample Size Calculations in Clinical Research</i> , 3rd Edition, Chapman and Hall (2017). 2. Chow S C and Liu J P, <i>Design and Analysis of Bioavailability and Bioequivalence Studies</i> , 3rd Edition, Chapman and Hall (2008). 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).	