AMITY UNIVERSITY
UTTAR PRADESH

FORMAT FOR COURSE CURRICULUM

Course Title: Clinical Data Management

Course Code: BIOF614 **Units: 02**

L	T	P/S	SW/FW	TOTAL CREDIT UNITS
02	0	0	0	02

Course Objectives:

Theory: Students will learn regulations impacting clinical data management, describe the framework for clinical data management operations, and processes involved in the set up of clinical data management.

Pre-requisites: UG in Bioinformatics/Biotechnology/Biomedical Science

Student Learning Outcomes:

- The student will practice clinical data submission and interpret the clinical results.
- The student will demonstrate skills to analyze and validate data for further analysis.

Course Contents/Syllabus- Theory:

	Weightage (%)
Module I	**10**
Descriptors/Topics: Basics of Clinical Trails Basic statistics for clinical trials, How to select and apply appropriate statistical methods to analyze data from clinical trials, presenting, interpreting and discussing the analyses	
Module II	**20**
Descriptors/Topics: Clinical Data Management-An Overview Data – Definition & Types, CRF Design for Clinical Trial, Query Resolution, Database update, drug safety and database locking, EDC System and 21CFR Part 11 compliance, Data Privacy: Implications for Clinical Operations, Data Management in Epidemiology, Data Management in Pharmacoeconomics.	
Module III	**20**

Descriptors/Topics: Project Management Data management plan, Project management for the clinical data manager, Vendor selection and management, Data management standards in clinical research, Design and development of data collection, Edit check design principles	
Module IV	**20**
Descriptors/Topics: Case Report Forms CRF Completion Guidelines, CRF printing and vendor selection, Data validation, programming and standards, Laboratory data handling, External data transfer, Patient-reported outcomes, CDM presentation at investigator meetings, Metrics for clinical trials, Systems Software Validation Issues – Clinical Trials Database Environment	
Module V	**20**
Descriptors/Topics: Quality Audits Audit – Definition, types & procedures, Audit standards, Audit trail & its role in authenticity of data, Audit plan, Audit by regulatory authorities, GMP, GDP & logistics, Preparing and delivering audit reports, What makes a good audit, New product development & GxP Regulations	

Pedagogy for Course Delivery:
The class will be taught using theory and practical method. In addition to solving practical problems, the course instructor will spend considerable time in understanding the concept of clinical trials.

Lectures: 25
Tutorial:
Presentation/ Seminar: 4
Class Test: 1
Total: 30

Assessment/ Examination Scheme:

Theory L/T (%)	Lab/Practical/Studio (%)	Total (%)
100%	NA	100%

Theory Assessment (L&T):

Continuous Assessment/Internal Assessment						End Term Examination
Components (Drop down)	**Class Test 1**	**Viva**	**Home Assignment**		**Attendance**	

Weightage (%)	15	5	10		5	70

Text:

1. Susanne Prokscha (2011), Practical Guide to Clinical Data Management, Third Edition, CRC Press; 3 edition (18 November 2011), ISBN-13: 978-1439848296.

2. Richard K Rondel (2000) Clinical Data Management, Second Edition. Wiley Publishing House. ISBN: 978-0-470-85335-1.

3. Design and Analysis of Clinical Trials : Concepts and Methodologies (Wiley Series in Probability and Statistics)by: Shein-Chung Chow, Jen-Pei Liu.