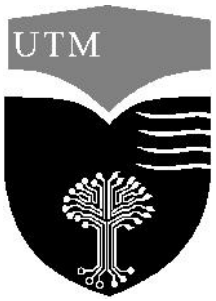

UNIVERSITY of TECHNOLOGY, MAURITIUS

School of Innovative Technologies and Engineering

Department of Applied Mathematical Sciences

Short Course Level 1
in
Statistical Analysis of Clinical Trials

COURSE DOCUMENT

VERSION 1.0
SCSACT v.1.0

October 2017

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SHORT COURSE LEVEL 1 IN STATISTICAL ANALYSIS OF CLINICAL TRIALS

A. Course Information

Clinical trials have traditionally remained one of the most important means for clinicians and scientists, in their quest of providing state-of-the art pharmaceuticals, biologics and medical devices in the pursuit of new drugs and treatments for human beings ailments. Nevertheless, gathering clinical data is a long way from actually meeting the required ends of the scientist's toolbox. In the sequel, important features of analysis, including the appropriateness of the methods used, need to be understood. This short course is an intensive twelve-day course, with three sessions scheduled for each day. A mini project will be expected to be submitted by the end of the course for assessment purposes.

B. Course Aims and Objectives

The course projects to add to the quality of the personnel undertaking statistical analyses of clinical data and train students who wish to pursue career in the field. It also serves as a good basis for those particularly wishing to broaden their statistical programming skills.

Upon successful completion of the course, students will be expected to have developed amongst others, a sound understanding in

- Employing graphical representations to represent and interpret clinical data
- The fundamentals of SAS® programming
- Phases of compilation and execution of SAS® programs.
- Output Delivery Systems

PART I - Regulations

C. Entry Requirements

A postgraduate degree or any other acceptable qualifications with significant statistical content.

Professional experience in the field would be an advantage.

D. Course Mode and Duration

Twelve days with three sessions of two and a half hours each scheduled on a day:

Session 1: 08:30 - 11:00
Session 2: 12:00 - 14:30
Session 3: 15:00 - 17:30

The time schedules are tentative.

Lecture and Practical consist of 90 contact hours with 60 hours for lecture and 30 hours practical.

E. Teaching and Learning Strategies

Lectures, Practical Sessions and Structured Discussions

F. Attendance Requirements

A minimum of 80% of attendance is required for a candidate to be eligible for a certificate of attendance or a short course level 1 in Statistical Analysis of Clinical Trials.
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G. Student Progress and Assessment

The student will be required to complete an assignment on the final day of the course.

H. Credit System and Award Classification

This course is equivalent to 5 credits.

For the award of the short course level 1 in Statistical Analysis of Clinical Trials, students will have to score at least 40% in the assignment. With a minimum of 80% attendance, award will be as per follows:

Overall Weighted Mark (y%)	Award
$y \geq 40$	Short Course Level 1
$y < 40$	Certificate of Attendance

I. Organisation and Management

Course Director and Coordinator: Dr Aslam A. E. F. SAIB

Contact Details: Telephone Number: 207 52 50
Email: asaib@umail.utm.ac.mu

Part II - Course Structure

J. Course Structure

DAY 1: INTRODUCTION AND BASICS	
Session1	Introduction to clinical trial - Basics
Session 2	Statistics and Hypothesis Testing
Session 3	Introduction to SAS® – Exploring SAS® Environment
DAY 2: BASICS OF CLINICAL TRIALS	
Session 1	Introduction to SAS® – Basics and Compilation
Session 2	Introduction to SAS®- Syntax errors
Session 3	Running SAS® programs
DAY 3: DATA ACCESS AND MANAGEMENT	
Session 1	SAS® Data Libraries
Session 2	Accessing and Reading Data – Hands-on
Session 3	PRINT procedure

DAY 4: DATA SORTING	
Session 1	Data Sorting and Manipulation using SAS®
Session 2	Data Sorting and Manipulation using SAS®
Session 3	Data Sorting and Manipulation using SAS® Hands-on practical
DAY 5: DATA MANAGEMENT	
Session 1	Reading Raw Data Files
Session 2	Reading Spreadsheets
Session 3	Practical
DAY 6: DATA STEP PROGRAMMING	
Session 1	Examining Data Errors
Session 2	Data Step Programming
Session 3	Data Step Programming
DAY 7: REPORTS	
Session 1	Data Errors
Session 2	Summary Reports
Session 3	Report and Tabulate

DAY 8: PLOTS	
Session 1	Hands-on practical on producing Summary Reports
Session 2	Producing Bar and Pie Charts
Session 3	Plots
DAY 9: GRAPHICS AND MACROS	
Session 1	Enhancing output
Session 2	Graphics –practical
Session 3	SAS® Macros
DAY 10: MACROS	
Session 1	SAS® Macros
Session 2	SAS® Macros
Session 3	Practical
DAY 11: FURTHER ANALYSIS	
Session 1	Further analysis with SAS®
Session 2	Further analysis with SAS®
Session 3	Review

DAY 12: CONCLUSION AND ASSIGNMENT	
Session 1	Efficiency Tips
Session 2	Assignment
Session 3	Assignment

K. Session Outline

Day 1: INTRODUCTION AND BASICS

Session 1: Introduction to clinical trial - Basics

Structure of the pharmaceutical industry, drug discovery process, phases of clinical trials, types of clinical trial designs, Role of the SAS® programmer in the pharmaceutical industry.

Session 2: Statistics and Hypothesis Testing

Parametric and non-parametric tests (χ), Hypothesis testing, ANOVA, mixed models

Session 3: Introduction to SAS® – Exploring SAS® Environment

Components of SAS® program, The SAS® Environment.

Day 2: BASICS OF CLINICAL TRIALS

Session 1: Introduction to SAS®- Basics and Compilation

Components of SAS®

Session 2: Introduction to SAS®- Syntax Errors

Syntax Rules, Diagnosing and correcting syntax errors.

Session 3: Running SAS® Programs

How to run SAS programs

Day 3: DATA ACCESS AND MANAGEMENT

Session 1: SAS® Data Libraries
Concept of SAS® Data Library

Session 2: Accessing and Reading Data – Hand-on
Practical

Session 3: Print Procedure

Investigate SAS® data using Contents and PRINT

Day 4: DATA SORTING

Session 1: Data Sorting and Manipulation using SAS®

Display selected Observations

Session 2: Data Sorting and Manipulation using SAS®

Sequencing and Grouping

Session 3: Data Sorting and Manipulation using SAS®- Hands-on Practical

Day 5: DATA MANAGEMENT

Session 1: Reading Raw Data Files

Column inputs and formatted inputs

Session 2: Reading Spreadsheets

Reading Spreadsheets and Creating Data Sets

Session 3: Practical

Practical

Day 6: DATA STEP PROGRAMMING

Session 1: Examining Data Errors

Examining Data Errors

Session 2: Data Step Programming
How data Step Processes Data

Session 3: Data Step Programming

Practical

Day 7: REPORTS

Session 1: Examining Data Reports

Types of Data Errors

Session 2: Summary Reports

Basic Summary Report

Session 3: Report and Tabulate

The REPORT and TABULATE procedures.

Day 8: PLOTS

Session 1: Hands-on Practical on Producing Summary Reports

Practical

Session 2: Producing BAR and Pie Charts

How to produce visual representations

Session 3: Plots

Graph plots

Day 9: GRAPHICS AND MACROS

Session 1: Enhancing Output

How to enhance SAS® output

Session 2: Practical

Practical

Session 3: SAS® Macros

SAS® Macros

Day 10: MACROS

Session 1: SAS® Macros

SAS® Macros

Session 2: SAS® Macros
SAS® Macros

Session 3: Practical

Day 11: FURTHER ANALYSIS WITH SAS®

Session 1: Further Analysis with SAS®

Session 2: Further Analysis with SAS®

Session 3: Review
Quick Recap

Day 12: CONCLUSION AND ASSIGNMENT

Session 1: Efficiency Tips

Session 2: Assignment

Session 3: Assignment