

BIOS6905: CLINICAL TRIALS

Effective Term

Semester A 2025/26

Part I Course Overview

Course Title

Clinical Trials

Subject Code

BIOS - Biostatistics

Course Number

6905

Academic Unit

Biostatistics (BIOS)

College/School

College of Computing (CC)

Course Duration

One Semester

Credit Units

3

Level

P5, P6 - Postgraduate Degree

Medium of Instruction

English

Medium of Assessment

English

Prerequisites

Nil

Precursors

Nil

Equivalent Courses

Nil

Exclusive Courses

Nil

Part II Course Details

Abstract

The goal of this class is to present an introduction to the practical aspects involved in the design and analysis of clinical trials. It describes logistical issues, basic principles, and philosophy alongside necessary methodology. Students will learn

the role of clinical trials in medical research, beginning with algorithmic and Bayesian dose finding (phase I) trials and then preliminary (phase II) and confirmatory (phase III) studies of efficacy. The need for blinding and various types of randomization and stratification will be presented. Methods of early stopping and design modification at interim analyses via group sequential and other adaptive designs will then be discussed, proceeding to techniques for analyzing studies with continuous, binary, longitudinal, quality of life, and survival data [see comment above for which topics you need here]. Design and analysis principles will be discussed for various study types including crossover, n-of-1, factorial, non-inferiority, randomized discontinuation, and multi-stage trials along with recent innovations such as umbrella and basket trials. The course will also present various computational tools and web-based applications useful in implementing the above objectives. At its end students will be able to be usefully employed in the design and analysis of clinical trials in the pharmaceutical industry and academia.

Course Intended Learning Outcomes (CILOs)

CILOs		Weighting (if app.)	DEC-A1	DEC-A2	DEC-A3
1	Explain the fundamental concepts and methods.	20	x	x	
2	Develop a solid understanding of the techniques.	20	x	x	
3	Conduct a thorough reading of the literature and know current state-of-the-art tools.	30	x	x	x
4	Apply the techniques and methods to real data applications.	30	x	x	x

A1: Attitude

Develop an attitude of discovery/innovation/creativity, as demonstrated by students possessing a strong sense of curiosity, asking questions actively, challenging assumptions or engaging in inquiry together with teachers.

A2: Ability

Develop the ability/skill needed to discover/innovate/create, as demonstrated by students possessing critical thinking skills to assess ideas, acquiring research skills, synthesizing knowledge across disciplines or applying academic knowledge to real-life problems.

A3: Accomplishments

Demonstrate accomplishment of discovery/innovation/creativity through producing /constructing creative works/new artefacts, effective solutions to real-life problems or new processes.

Learning and Teaching Activities (LTAs)

LTAs		Brief Description	CILO No.	Hours/week (if applicable)
1	Lectures	Learning through teaching is primarily based on lectures	1, 2, 3, 4	3 hours/week
2	Assignments	Learning through take-home assignments helps students understand the key concepts and acquire the techniques	1, 2, 3, 4	After class

Assessment Tasks / Activities (ATs)

	ATs	CILO No.	Weighting (%)	Remarks ("- " for nil entry)	Allow Use of GenAI?
1	Assignments	1, 2, 3, 4	40	Help to train students with basic knowledge, concepts, and analysis techniques	Yes
2	Midterm/quizzes	1, 2, 3, 4	20	Test students' capabilities in applying the knowledge to solve relevant problems	No

Continuous Assessment (%)

60

Examination (%)

40

Examination Duration (Hours)

2

Minimum Continuous Assessment Passing Requirement (%)

40

Minimum Examination Passing Requirement (%)

35

Additional Information for ATs

Examination questions are designed to see how well students have achieved the learning objectives and acquired the requisite techniques for problem-solving.

To pass the course, students are required to obtain a minimum of 40% in continuous assessment and a minimum of 35% in the examination.

Assessment Rubrics (AR)**Assessment Task**

Assignments (for students admitted before Semester A 2022/23 and in Semester A 2024/25 & thereafter)

Criterion

Problem solving skills

Excellent

(A+, A, A-) Consistently exhibits adept comprehension of clinical trials principles and their practical implementation

Good

(B+, B, B-) Sufficiently applies clinical trials concepts to moderately complex problems

Fair

(C+, C, C-) Demonstrates a moderate understanding of clinical trials concepts and their practical application to intermediate-level problems.

Marginal

(D) Displays basic grasp of clinical trials concepts and their application to straightforward problems.

Failure

(F) Shows limited comprehension of clinical trials concepts and lacks the ability to apply them to problem-solving

Assessment Task

Midterm/quizzes (for students admitted before Semester A 2022/23 and in Semester A 2024/25 & thereafter)

Criterion

Problem solving based on comprehensive understanding

Excellent

(A+, A, A-) Exhibits a thorough grasp of clinical trials concepts and effectively applies them to intricate problems

Good

(B+, B, B-) Displays sufficient understanding of clinical trials concepts and effectively applies them to moderately complex problems

Fair

(C+, C, C-) Exhibits a moderate level of comprehension regarding clinical trials concepts and effectively applies them to intermediate-level problems.

Marginal

(D) Shows basic comprehension of clinical trials concepts and applies them to straightforward problems

Failure

(F) Displays limited grasp of clinical trials concepts and lacks the ability to apply them to problem-solving

Assessment Task

Examination (for students admitted before Semester A 2022/23 and in Semester A 2024/25 & thereafter)

Criterion

Problem solving based on comprehensive understanding

Excellent

(A+, A, A-) Consistently exhibits a deep understanding of clinical trials concepts and effectively applies them to complex problems

Good

(B+, B, B-) Effectively applies clinical trials concepts to moderately complex problems, demonstrating sufficient understanding

Fair

(C+, C, C-) Applies clinical trials concepts to intermediate-level problems with a moderate level of understanding.

Marginal

(D) Applies clinical trials concepts to simple problems with a basic understanding

Failure

(F) Lacks understanding of clinical trials concepts and cannot apply them to problem-solving

Assessment Task

Assignments (for students admitted from Semester A 2022/23 to Summer Term 2024)

Criterion

Problem solving skills

Excellent

(A+, A, A-) Consistently exhibits adept comprehension of clinical trials principles and their practical implementation

Good

(B+, B) Sufficiently applies clinical trials concepts to moderately complex problems

Marginal

(B-, C+, C) Displays basic grasp of clinical trials concepts and their application to straightforward problems.

Failure

(F) Shows limited comprehension of clinical trials concepts and lacks the ability to apply them to problem-solving

Assessment Task

Midterm/quizzes (for students admitted from Semester A 2022/23 to Summer Term 2024)

Criterion

Problem solving based on comprehensive understanding

Excellent

(A+, A, A-) Exhibits a thorough grasp of clinical trials concepts and effectively applies them to intricate problems

Good

(B+, B) Displays sufficient understanding of clinical trials concepts and effectively applies them to moderately complex problems

Marginal

(B-, C+, C) Shows basic comprehension of clinical trials concepts and applies them to straightforward problems

Failure

(F) Displays limited grasp of clinical trials concepts and lacks the ability to apply them to problem-solving

Assessment Task

Examination (for students admitted from Semester A 2022/23 to Summer Term 2024)

Criterion

Problem solving based on comprehensive understanding

Excellent

(A+, A, A-) Consistently exhibits a deep understanding of clinical trials concepts and effectively applies them to complex problems

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(B+, B) Effectively applies clinical trials concepts to moderately complex problems, demonstrating sufficient understanding

Marginal

(B-, C+, C) Applies clinical trials concepts to simple problems with a basic understanding

Failure

(F) Lacks understanding of clinical trials concepts and cannot apply them to problem-solving

Part III Other Information**Keyword Syllabus**

Clinical trials, randomization, data monitoring, phase I trials, phase II trials, phase III trials, adaptive trials.

Reading List**Compulsory Readings**

Title	
1	Nil

Additional Readings

Title	
1	Fundamentals of Clinical Trials, 5th ed. (Springer) by Friedman, L.M., Furberg, C.D., and DeMets, D.L. , et al.
2	Introduction to Statistical Methods for Clinical Trials (Chapman & Hall/CRC) by Cook, T.D., and DeMets, D.L.
3	Bayesian Designs for Phase I-II Clinical Trials (Chapman & Hall/CRC) by Yuan, Y., Nguyen, H.Q., and Thall, P.