

**City University of Hong Kong
Course Syllabus**

**offered by Department of Biostatistics
with effect from Semester A 2024/25**

Part I Course Overview

Course Title: Clinical Trials

Course Code: BIOS6905

Course Duration: 1 Semester

Credit Units: 3 CUs

Level: P6

Medium of Instruction: English

Medium of Assessment: English

Prerequisites:
(Course Code and Title) Nil

Precursors:
(Course Code and Title) Nil

Equivalent Courses:
(Course Code and Title) Nil

Exclusive Courses:
(Course Code and Title) Nil

Part II Course Details

1. 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.

2. Course Intended Learning Outcomes (CILOs)

(CILOs state what the student is expected to be able to do at the end of the course according to a given standard of performance.)

No.	CILOs	Weighting (if applicable)	Discovery-enriched curriculum related learning outcomes (please tick where appropriate)		
			A1	A2	A3
1.	Explain the fundamental concepts and methods.	20%	✓	✓	
2.	Develop a solid understanding of the techniques.	20%	✓	✓	
3.	Conduct a thorough reading of the literature and know current state-of-the-art tools.	30%	✓	✓	✓
4.	Apply the techniques and methods to real data applications.	30%	✓	✓	✓
		100%			

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.

3. Learning and Teaching Activities (LTAs)

(LTAs designed to facilitate students' achievement of the CILOs.)

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

4. Assessment Tasks/Activities (ATs)

(ATs are designed to assess how well the students achieve the CILOs.)

Assessment Tasks/Activities	CILO No.				Weighting	Remarks
	1	2	3	4		
Continuous Assessment: 60%						
Assignments	✓	✓	✓	✓	40%	Help to train students with basic knowledge, concepts, and analysis techniques
Midterm/quizzes	✓	✓	✓	✓	20%	Test students' capabilities in applying the knowledge to solve relevant problems
Examination: 40% (duration: 3 hours)	✓	✓	✓	✓	40%	Examination questions are designed to see how well students have achieved the learning objectives and acquired the requisite techniques for problem-solving
					100%	

5. Assessment Rubrics

(Grading of student achievements is based on student performance in assessment tasks/activities with the following rubrics.)

Applicable to students admitted before Semester A 2022/23 and in Semester A 2024/25 & thereafter

Assessment Task	Criterion	Excellent (A+, A, A-)	Good (B+, B, B-)	Fair (C+, C, C-)	Marginal (D)	Failure (F)
1. Assignments	Problem solving skills	Consistently exhibits adept comprehension of clinical trials principles and their practical implementation	Sufficiently applies clinical trials concepts to moderately complex problems	Demonstrates a moderate understanding of clinical trials concepts and their practical application to intermediate-level problems.	Displays basic grasp of clinical trials concepts and their application to straightforward problems.	Shows limited comprehension of clinical trials concepts and lacks the ability to apply them to problem-solving
2. Midterm/quizzes	Problem solving based on comprehensive understanding	Exhibits a thorough grasp of clinical trials concepts and effectively applies them to intricate problems	Displays sufficient understanding of clinical trials concepts and effectively applies them to moderately complex problems	Exhibits a moderate level of comprehension regarding clinical trials concepts and effectively applies them to intermediate-level problems.	Shows basic comprehension of clinical trials concepts and applies them to straightforward problems	Displays limited grasp of clinical trials concepts and lacks the ability to apply them to problem-solving
3. Examination	Problem solving based on comprehensive understanding	Consistently exhibits a deep understanding of clinical trials concepts and effectively applies them to complex problems	Effectively applies clinical trials concepts to moderately complex problems, demonstrating sufficient understanding	Applies clinical trials concepts to intermediate-level problems with a moderate level of understanding.	Applies clinical trials concepts to simple problems with a basic understanding	Lacks understanding of clinical trials concepts and cannot apply them to problem-solving

Applicable to students admitted from Semester A 2022/23 to Summer Term 2024

Assessment Task	Criterion	Excellent (A+, A, A-)	Good (B+, B)	Marginal (B-, C+, C)	Failure (F)
1. Assignments	Problem solving skills	Consistently exhibits adept comprehension of clinical trials principles and their practical implementation	Sufficiently applies clinical trials concepts to moderately complex problems	Displays basic grasp of clinical trials concepts and their application to straightforward problems.	Shows limited comprehension of clinical trials concepts and lacks the ability to apply them to problem-solving
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Part III Other Information (more details can be provided separately in the teaching plan)

1. Keyword Syllabus

(An indication of the key topics of the course.)

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

2. Reading List

2.1 Compulsory Readings

(Compulsory readings can include books, book chapters, or journal/magazine articles. There are also collections of e-books, e-journals available from the CityU Library.)

Nil.

2.2 Additional Readings

(Additional references for students to learn to expand their knowledge about the subject.)

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.