

MATH 654: Clinical Trials Design and Analysis

Spring 2023 Course Syllabus

NJIT Academic Integrity Code: All Students should be aware that the Department of Mathematical Sciences takes the University Code on Academic Integrity at NJIT very seriously and enforces it strictly. This means that there must not be any forms of plagiarism, i.e., copying of homework, class projects, or lab assignments, or any form of cheating in quizzes and exams. Under the University Code on Academic Integrity, students are obligated to report any such activities to the Instructor.

COURSE INFORMATION

Course Description: Statistical methods and issues in the design of clinical trials and analysis of their data. Topic include clinical trial designs for phases 1-4, randomization principle and procedures, analysis of pharmacokinetic data for bioequivalence, multi-center trials, categorical data analysis, survival analysis, longitudinal data analysis, interim analysis, estimation of sample size and power, adjustment for multiplicity, evaluation of adverse events, and regulatory overview.

Number of Credits: 3

Prerequisites: Math 665 or equivalent with Departmental Approval

Course-Section and Instructors:

Course-Section	Instructor
Math 654-102	Professor W. Guo

Office Hours for All Math Instructors: [Spring 2023 Office Hours and Emails](#)

Required Textbook:

Title	<i>Clinical Trial Design: Bayesian and Frequentist Adaptive Methods</i>
Author	Guosheng Yin
Edition	1st
Publisher	Wiley
ISBN #	ISBN-10: 0470581719, ISBN-13: 978-0470581711

University-wide Withdrawal Date: The last day to withdraw with a W is **Monday, April 3, 2023**. It will be strictly enforced.

POLICIES

DMS Course Policies: All DMS students must familiarize themselves with, and adhere to, the [Department of Mathematical Sciences Course Policies](#), in addition to official [university-wide policies](#). DMS takes these policies very seriously and enforces them strictly.

Grading Policy: The final grade in this course will be determined as follows:

Homework	25%
Project	15%
Midterm Exam	25%
Final Exam	35%

Your final letter grade will be based on the following tentative curve.

A	90 - 100	C+	75 - 79
B+	85 - 89	C	70 - 74
B	80 - 84	F	0 - 69

Attendance Policy: Attendance at all classes will be recorded and is **mandatory**. Please make sure you read and fully understand the [Math Department's Attendance Policy](#).

Exams: There will be one exams during the semester and a cumulative final exam during the final exam week:

Midterm Exam	Week 9
Final Exam Period	May 5 - May 11, 2023

The final exam will test your knowledge of all the course material taught in the entire course. Make sure you read and fully understand the [Math Department's Examination Policy](#). This policy will be strictly enforced.

Makeup Exam Policy: There will be **NO MAKE-UP QUIZZES OR EXAMS** during the semester. In the event an exam is not taken under rare circumstances where the student has a legitimate reason for missing the exam, the student should contact the Dean of Students office and present written verifiable proof of the reason for missing the exam, e.g., a doctor's note, police report, court notice, etc. clearly stating the date AND time of the mitigating problem. The student must also notify the Math Department Office/Instructor that the exam will be missed.

Cellular Phones: All cellular phones and other electronic devices must be switched off during all class times.

ADDITIONAL RESOURCES

Further Assistance: For further questions, students should contact their instructor. All instructors have regular office hours during the week. These office hours are listed on the Math Department's webpage for [Instructor Office Hours and Emails](#).

Accommodation of Disabilities: The Office of Accessibility Resources and Services (OARS) offers long term and temporary accommodations for undergraduate, graduate and visiting students at NJIT.

If you are in need of accommodations due to a disability please contact Scott Janz, Associate Director of Disability Support Services at [973-596-5417](tel:973-596-5417) or via email at scott.p.janz@njit.edu. The office is located in Kupfrian Hall, Room 201. A Letter of Accommodation Eligibility from the Office of Accessibility Resources and Services office authorizing your accommodations will be required.

For further information regarding self identification, the submission of medical documentation and additional support services provided please visit the Office of Accessibility Resources and Services (OARS) website at:

<https://www.njit.edu/accessibility/>

Important Dates (See: [Spring 2023 Academic Calendar](#), Registrar)

Date	Day	Event
January 17, 2023	Tuesday	First Day of Classes
January 23, 2023	Monday	Last Day to Add/Drop Classes
March 13, 2023	Monday	Spring Recess Begins
March 18, 2023	Saturday	Spring Recess Ends
April 3, 2023	Monday	Last Day to Withdraw
April 7, 2023	Friday	Good Friday - No Classes
May 2, 2023	Tuesday	Friday Classes Meet
May 2, 2023	Tuesday	Last Day of Classes
May 3 - May 4, 2023	Wednesday and Thursday	Reading Days
May 5 - May 11, 2023	Friday to Thursday	Final Exam Period

Course Outline				
Date	Lecture	Sections	Topic	Assignment
Week 1	1	Lecture Notes	Introduction to Epidemiology	Homework 1
Week 2	2	Chapter 1 and Lecture Notes	Introduction to Clinical Trials	
Week 3	3	Chapter 4 and Lecture Notes	Phase I Clinical Trials	Homework 2
Week 4	4	Chapter 5 and Lecture Notes	Phase II Clinical Trials	
Week 5	5	Chapter 2 and	Phase III Clinical Trials	Homework 3

		Lecture Notes		
Week 6	6	Chapter 7 and Lecture Notes	Randomization	
Week 7	7	Sections 6.1-6.3 and Lecture Notes	Sample Size Calculations	Homework 4
Week 8			Spring Recess- No Classes Scheduled	
Week 9			MIDTERM EXAM	
Week 10	8	Section 6.6 and Lecture Notes	Group Sequential Methods (I)	Clinical Trials Project
Week 11	9	Lecture Notes	Group Sequential Methods (II)	Homework 5
Week 12	10	Lecture Notes	Multiple Comparisons Procedures (I)	
Week 13	11	Lecture Notes	Multiple Comparisons Procedures (II)	Homework 6
Week 14	12	Section 6.7 and Lecture Notes	Introduction to Adaptive Design	
Week 15			Students Project Presentation	
Week 16			FINAL EXAM	

*Updated by Professor W. Guo - 1/5/2023
Department of Mathematical Sciences Course Syllabus, Spring 2023*