

IMPORTANT: This syllabus form should be submitted to OAA (gsbs_academic_affairs@uth.tmc.edu) a week before the start of each semester.

NOTE to STUDENTS: If you need any accommodations related to attending/enrolling in this course, please contact one of the Graduate School's 504 Coordinators, Cheryl Spitzenberger or Natalie Sirisaengtaksin. We ask that you notify GSBS in advance (preferably at least 3 days before the start of the semester) so we can make appropriate arrangements.

<p>Term and Year: Spring 2023</p> <p>Course Number and Course Title: GS01 1033: Introductory Biostatistics and Clinical Trials</p> <p>Credit Hours: 3</p> <p>Meeting Location: Building/Room#: TR BRC 284</p> <p>WebEx/Zoom Link: N/A</p>	<p>Program Required Course: Yes</p> <p>Approval Code: No</p> <p>Audit Permitted: Yes</p> <p>Classes Begin: January 10, 2023</p> <p>Classes End: April 20, 2023</p>								
<p>Class Meeting Schedule</p>									
<table border="1"> <thead> <tr> <th data-bbox="107 974 808 1018">Day</th> <th data-bbox="808 974 1503 1018">Time</th> </tr> </thead> <tbody> <tr> <td data-bbox="107 1018 808 1060">Tuesday & Thursday</td> <td data-bbox="808 1018 1503 1060">4:00 – 5:15 pm</td> </tr> <tr> <td data-bbox="107 1060 808 1102"> </td> <td data-bbox="808 1060 1503 1102"> </td> </tr> <tr> <td data-bbox="107 1102 808 1138"> </td> <td data-bbox="808 1102 1503 1138"> </td> </tr> </tbody> </table>	Day	Time	Tuesday & Thursday	4:00 – 5:15 pm					
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<p>Course Director Name and Degree: Suyu Liu, PhD Title: Assistant Professor Department: Biostatistics Institution: UTH X MDACC Email Address: syliu@mdanderson.org Contact Number: 713-563-4280</p> <p>Course Co-Director/s: Name and Degree: Ying Yuan, PhD Title: Professor Department: Biostatistics Institution: UTH X MDACC Email Address: yyuan@mdanderson.org Contact Number: 713-569-4271</p>	<p>Instructor/s</p> <p>1. Name and Degree: Suyu Liu, PhD Institution: MDACC Email Address : syliu@mdanderson.org</p> <p>2. Name and Degree: Ying Yuan, PhD Institution: MDACC Email Address : yyuan@mdanderson.org</p> <p>3. Name and Degree Institution: Email Address</p>								

Teaching Assistant: (if any) Name and Email Address:	
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Course description:

This course provides an overview of statistical methodology useful in the practice of modern biostatistics. There are two major topics covered in the course at an introductory level: biostatistics for epidemiology and clinical trial design. More specific topics are listed in the attached daily syllabus.

Textbook/Supplemental Reading Materials

- **Statistics for Epidemiology**, by Nicholas Jewell. Publisher: Chapman & Hall/CRC
- **Model-Assisted Bayesian Designs for Dose Finding and Optimization**, by Ying Yuan, Ruitao Lin and Jack Lee. Publisher: Chapman & Hall/CRC
- **Software:** R package (can be downloaded from <https://www.r-project.org/>)

Course Objective/s:

This course provides an overview of statistical methodology useful in the practice of modern biostatistics.

Specific Learning Objectives:

1. Understand the basic concepts of experimental design.
2. Know the common types of the observational studies and their characteristics.
3. Master the basic skills to analyze the disease-exposure association study data.
4. Understand the phase of clinical trials and the commonly used designs for each phase5.

Student responsibilities and expectations:

Homework: Each of the two major parts will include approximately 2-3 assignments, at least one of which will be data based. All students are required to complete the assignments. Homework will be submitted at the beginning of class on the due date. If circumstances beyond the student's control arise and an assignment cannot be submitted on the due date, an instructor should be contacted prior to the due date. With an instructor's permission, late homework may be accepted within one week of the due date. All decisions will be made on an individual student basis and the final decision rests with the instructor assigning the homework. **A penalty of 10 percentage points will be applied to late homework.**

Website: <http://odin.mdacc.tmc.edu/~yyuan/> has more information about the Biostatistics part of the course and datasets for the homework.

Examinations: There will be one in-class exam and one final project in the course.

Course Grade: The material covered in the classroom serves two different courses, STAT 453 (undergraduate) and 553 (graduate). Although the lectures will cover the same material for both courses, those enrolled in STAT 553 will be required to answer either additional questions or more challenging questions on both the homework assignments and in-class quizzes. Although the requirements for the two courses are the same, different grading scales will be applied to the two courses according to their relative level. Both courses will be graded on the following component basis.

Component %

Homework	50
Midterm Exam	30
Final Project	20

Grading System: Letter Grade (A-F)

Student Assessment and Grading Criteria : *(May include the following:)*

Percentage	Description
Homework (50 %)	
Midterm Exams (30 %)	
Final Project (20 %)	

CLASS SCHEDULE (see attached)

Disability Statement

Any student with a disability requiring accommodations in this course is encouraged to contact me after class or during office hours. Additionally, students will also need to contact Disability Support Services in the Ley Student Center.

TENTATIVE DAILY SYLLABUS

Week	Date		Topic	Readings*	Instructor
1	1/10	Tue	Introduction	SE: 1, 2	Liu
	1/12	Thu	Study Design	SE: 3, 5	Liu
2	1/17	Tue	Disease-Exposure Association	SE: 4	Liu
	1/19	Thu	Contingency Tables: Association	SE: 6	Liu
3	1/24	Tue	Contingency Tables: Confounding	SE: 9	Liu
	1/26	Thu	Contingency Tables: Interaction	SE: 10	Liu
4	1/31	Tue	Logistic Regression: introduction	SE: 12	Liu
	2/2	Thu	Logistic Regression: estimation	SE: 13	Liu
5	2/7	Tue	Logistic Regression: diagnosis	SE: 13	Liu
	2/9	Thu	Spring Recess		
6	2/14	Tue	Matched studies	SE: 16	Liu
	2/16	Thu	Matched studies	SE: 16	Liu
7	2/21	Tue	TBA		Liu
	2/23	Thu	Midterm Exam		Liu
8	2/28	Tue	Introduction to clinical trials		Yuan
	3/2	Thu	Introduction to clinical trials		Yuan
9	3/7	Tue	Bayesian statistics	MA: 1	Yuan
	3/9	Thu	Bayesian statistics	MA: 1	Yuan
10	3/14	Tue	Spring Break		
	3/16	Thu	Spring Break		
11	3/21	Tue	3+3 design, CRM	MA: 2	Yuan
	3/23	Thu	BMA-CRM	MA: 2	Yuan
12	3/28	Tue	Bayesian optimal interval design	MA: 3	Yuan
	3/30	Thu	Drug combination trials	MA: 4	Yuan
13	4/4	Tue	Handle late-onset toxicity	MA: 5	Yuan
	4/6	Thu	Finding optimal biological dose	MA: 8	Yuan
14	4/11	Tue	Phase II trial design		Yuan
	4/13	Thu	Basket trial design		Yuan
15	4/18	Tue	Final project presentation		Yuan
	4/20	Thu	Final project presentation		Yuan

*SE: Statistics for Epidemiology

*MA: Model-Assisted Bayesian Designs for Dose Finding and Optimization