2022 UConn Statistics in Pharmaceuticals Short Course

Course Plan

The course will teach the basics in pharmaceutical statistics using a project-based Learning approach. The content of the course is heavily enriched by real drug examples across different therapeutic area. And the students will learn by actively engaging in real-world project for drug development. It will also cover the use of the software in design and analysis of clinical trials.

Students can choose to be fully remote during the course. However, as the instructors will be on campus on July 25, 2022, we encourage students to be there in person as well, if it is feasible and take advantage of the planned afternoon Lunch and Meet.

Assessment:

30% attendance

10% Homework 1, 10% Homework 2, 10% Homework 3: Homework is due on **August 5th**. Office hours will be provided as indicated below.

40% project slides and presentation. As indicated in the course description, we will take a project based learning approach. The project we will work on is a real drug. Background materials and data are available in the course content area. The background material includes the phase II and III protocols and related publications for Brodalumab-a drug to treat Psoriasis and other autoimmune disease. In addition, it includes the full package for the FDA advisory committee meeting, one summary from sponsor and one summary from FDA. The data are **simulated** pseudo data to mimic the summary statistics in the publication of results. It would be beneficial to read the full package of background materials to understand the big picture of drug development process, especially the clinical stage.

You are encouraged to form teams by yourselves to work on the course project. You may create a post in Discussion Board to recruit members. If you successfully form a team, please inform me at qiqi.deng@uconn.edu and Dooti.roy@uconn.edu by **5:00PM EST on July 30**. If I don't hear from you before that, you will be assigned to one of the teams and the teams will be announced by **August 1**. You will have one more chance to switch teams by sending emails to me before **5:00PM EST on August 2.** After that, the teams will start to work on the projects. We encourage the team members to set up calls as needed among themselves to discuss the project. If you have any questions, feel free to reach out to us by email or come to our office hours.

Included in your course is the access to Statistics in Pharmaceuticals (SIP) conference **August 22-23**. We will provide a code to waive your registration fee. It can be on-site or virtual attendance. Although it is not required, it is encouraged that you may submit your poster for SIP conference. The instruction for submission in at https://events.stat.uconn.edu/SIP2022/#poster. The submission deadline is **August 16**.

Once completed, please send your presentation to us. On **August 19**, we will have presentations for the course project. Each team will have up to 30 minutes to present. Details slot and order will be provided later based on number of teams formed. Dooti and Qiqi will grade your project work based on your presentation.

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WEEK 1

Days	Time	Topic	Presenter	Homework	Office hour
Monday 7/25/2022 **(Instructors on campus)**	9:00 - 10:30	Overview of phase I/II/III clinical trial Development process	Qiqi Deng Dooti Roy (Room: AUST 344 for students on site)		
	10:30 -10:45	Break			
	10:45 -11:30	Case study (Part 1): Background of the project, Clinical Development Plan			
	12:00 – 2:00	Lunch and Meet			
Tuesday 7/26/2022	9:30-10:25	Case study (Part 2): Introduction to Phase 2 protocol, and Statistical Considerations	Dooti Roy	Information relevant for the project (case study)	
	10:25-10:35	Break			
	10:35-11:30	Case study (Part 3): Introduction to Phase 3 protocol, and Statistical Considerations			
Wednesday 7/27/2022	8:30-9:45	Role of Statisticians in a clinical trial conduct. Trial statistical analysis plan (TSAP) Trial oversight meetings during trial conduct Database Lock and Clinical Study Report	Dooti Roy		
	9:45-10:00	Break			
	10:00-12:00	Data Standard (CDISC/SDTM/ADaM) and statistical programming of clinical trials	Hongli Lu		
Thursday 7/28/2022	9:30-11:30	Basics for sample size calculation in clinical trials: methodology, examples and implementation using software (1) Normally distributed Endpoint (2) Binary endpoint (3) Continuous endpoint	Qiqi Deng	HW1	
Friday 7/29/2022	9:30-11:30	Estimand in clinical trials Examples of intercurrent events and missing data across different Therapeutic areas.	Qiqi Deng	HW2	2-3pm

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WEEK 2

Days	Time	Topic	Presenter	Homework	Office hour
Monday 8/1/2022	**CCD Career Development Day (This is a special activity organized by UConn CCD. It is integrated into the short course agenda for easy access of the information.)**		UConn CCD		
	10:00-10:30 a.m.	Introductions and Opening Activity			
	10:30-11:30 a.m.	Finding Jobs and Internships Understanding Job Postings and Applicant Tracking Systems			
	11:30 a.m.-12:30 p.m.	*Lunch*			
	12:30-2:00 p.m.	Résumé/CV Presentation and Lab			
	2:00-3:00 p.m.	Building a LinkedIn Profile/Optimizing Your Use of LinkedIn			
Tuesday 8/2/2022	9:30-11:30	Multiplicity adjustment • A review of FDA and EMA guidance about multiplicity adjustment	Dooti Roy	HW3	2-3pm
Wednesday 8/3/2022	9:30-11:30	Adaptive Design	Qiqi Deng		
Thursday 8/4/2022	9:30-11:30	Leverage historical data and data synthesis. • Borrowing historical information • Borrowing adult trial data for pediatric development • Synthesis of data from different resources.	Dooti Roy		
Friday 8/12/2022		Office hour only for project related questions	Qiqi Deng Dooti Roy		1-2pm
Friday 8/19/2022	11:00-12:30 1:30-3	Project presentation	Qiqi Deng Dooti Roy and all students		