

Introduction to Translational Medicine(轉譯醫學導論)-S452300

Course Coordinator: Guey Chuen (Oscar) Perng

Place: 11th floor Lecture Room;

Time: Every Friday from 1:00pm to 3:00pm; Credits: 2

週次 Week	Class Date	Lecture	進度 Progress Description
1	2/26	Oscar Perng	Course introduction
2	3/5	Sunny Wu	Drug discovery and design I
3	3/12	Sunny Wu	Drug discovery and design II
4	3/19	Jenn-Wei Chen	Product investigation and development, and The Food and Drug administration
5	3/26	Grace Lo	Institutional Review Boards
6	4/2	National Holiday	
7	4/9	Sunny Wu	Informed consent and Privacy of subjects
8	4/16	Oscar Perng	Points to consider: the principal investigator, site selection and budget negotiations
9	4/23	Grace Lo	Early phase clinical trials design
10	4/30	Oscar Perng	Going global: International Trials, Global Good Clinical Practice/The clinical research team
11	5/7	Oscar Perng	Clinical study protocol elements and statistical considerations
12	5/14	Oscar Perng	Study monitoring & the study site initiation
13	5/21	Jenn-Wei Chen	Safety reporting: definitions and reporting requirements
14	5/28	Jenn-Wei Chen	Compliance and quality assurance: audits and inspections
15	6/4	Oscar Perng	Conflicts of interest
16	6/11	Oscar Perng	Group Discussion
17	6/18	Oscar Perng	Hand in class assignments
18	6/25	Oscar Perng	Project Presentation

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Class Assignments:

Do short presentation/report on writing an IRB protocol and writing a proposal for the FDA approval.

1. Identify a name of concept drug/biomarker
2. How to test the mode of action of the target drug
3. How to apply for IND/drug
4. How to apply for clinical trials/ performance
5. How to file for approval of FDA of your concept drug.