

臺大臨床藥學研究所

臺大臨床醫學研究所

藥品臨床試驗

Clinical Trial on Pharmaceutical Products

111 學年度第一學期

課號：451 U0500

課程負責教師：楊志新醫師

地點：臺大醫學院基礎醫學大樓 2 樓 201 講堂

時間：星期二下午 3:30-5:20

週次	日期	課程內容	授課教師
1	09/06	Introduction to clinical trials Definition, classifications, phases, resources, organizations, regulations Clinical trial protocol design Idea formation to development of a protocol, basic components of a protocol, design of a protocol Conduct of a clinical trial Initiation, registration, randomization, data collection, scheduling, safety monitoring, study material management	楊志新
2	09/13	Introduction to regulatory requirements in clinical trials and birth of a new drug Present regulatory requirements and all applicable laws and regulations for clinical trial, bridging study evaluation and new drug applications, and current procedures for the authorization.	陳瑩如
3	09/20	Non-clinical requirements to initiate clinical trials Animal toxicology, pharmacology, pharmacokinetics, CMC	林滿玉
4	09/27	Pharmacovigilance	高純琇
5	10/04	Clinical Protocol Review- Regulator's perspectives	徐麗娟
6	10/11	Cardiovascular diseases trials	徐莞曾
7	10/18	Informed consent, institutional review board and subject protection Basic component of an informed consent, ethical consideration of a clinical trial Audit and inspection Quality assurance, regulatory inspection	沈盈君
8	10/25	Statistical considerations in randomized clinical trials	蕭金福
9	11/01	Early clinical trials and phase I center	林家齊

週次	日期	課程內容	授課教師
10	11/08	Operation in Clinical Trials - the Role of CRA	孫婷婷
11	11/15	本校校慶	
12	11/22	Strategy and Policy for Clinical Development of International Pharmaceutical Company	陳純誠
13	11/29	Neuropsychiatric diseases trials	張鎔麒
14	12/05(一) 上午 10:20-12:10 教室未定	Infectious diseases trials	張上淳
14	12/06 下午 4:30-5:20	Oncology trials ※課前須觀看預錄影片	許駿
15	12/13	臨床試驗常遇到之問題及結果判讀	楊志新
16	12/20	Final exam (15:30 - 17:20)	