



**Universitas Gadjah Mada**

Faculty of Pharmacy

Doctoral Study Program in Pharmaceutical Science

### **Clinical Trial (3,2 ECTS/ 2 CSU)**

Code/Status	FAS3220116/Elective
Module designation	Doctoral Study Program in Pharmaceutical Science
Semester(s) in which the module is taught	1
Person responsible for the module	Prof. Dr. Zullies Ikawati, Apt. Dr. Fita Rahmawati, SpFRS, Apt.
Language	Indonesian
Teaching methods	Problem based learning. Presentation and discussion. 100 minutes/weekly and 14 weeks during the semester
Workload (incl. contact hours, self-study hours)	100 minutes of in-class lectures
Credit points	3,2 ECTS/2 CSU
Required and recommended prerequisites for joining the module	-
Module objectives/intended learning outcomes	Students are well-versed in the concept of Good Clinical Practice, emphasizing the importance of ethical and quality standards in clinical trials. Additionally, they possess the skills to formulate a protocol for randomized clinical trials (RCT), showcasing their comprehensive understanding of both theoretical and practical aspects of clinical research.
Content	This course teaches ethical aspects in clinical research (Good Clinical Practice) and the ability to develop good clinical trial protocols
Examination forms	
Study and examination requirements	A-E. Project/case 50%. Presentation and discussion 50%.
Reading list	<b>Main</b> (1) GCP Module from <a href="https://gcp.nidatraining.org">https://gcp.nidatraining.org</a> (2) Guidelines for Good Clinical Trials in Indonesia, BPOM, 2016
Date of last amendment	<b>Aug 1, 2023</b>