

Course	Critical Path Research Management
Course No.	
Credits	2 Credits
Grade	1 Year
Timetable	Fall AB Mon 6, 7
Instructor	Koichi Hashimoto, Masafumi Muratani, Kenichi Yanagi, Keiko Fujie, Hideo Tsurushima, Takahiro Kojima
Course Overview	Scientific empirical studies on safety and effectiveness are indispensable in the development of medicine, therapeutic instruments, medical materials, and therapeutic/diagnostic equipment. These days, scientific empirical studies on safety and effective has also become indispensable in the development of functional foods, etc. from the viewpoint of preventive medicine. In addition, rapid development of technical seeds is strongly required in accordance with the needs of the medical care site. Under these circumstances, this course aims to equip students with importance to manage R&D strategically and to understand the existence of various jobs related to medical/pharmaceutical/health, not only from the scientific point of view, but also from the technical management point of view.
Remarks	Conducted in English.
Course Type	Lectures
Link between Course Objectives and Activities	To study how social needs related to Food and Health is connected to research and development in laboratories through the topic of critical path and translational research in medicine (especially, development of drugs and medical devices).
Academic Goal	<ol style="list-style-type: none"> 1. Students will be able to explain the process of medical drug and device development. 2. Students will be able to explain the importance of pre-clinical and clinical studies evaluating the safety and efficacy of medical drugs and devices. 3. Students will be able to explain the social situation of medical drug and device development, and the organization and authorized people concerning drug development. 4. Students will be able to explain the importance of technology for drug and device development and intellectual property.
Course Schedule	<ol style="list-style-type: none"> 1. Introduction to critical path research and translational research (Koichi Hashimoto) 2. Drug development I (Drug discovery) (Masafumi Muratani) 3. Drug development II (Pre-clinical and clinical studies) (Keiko Fujie) 4. High-technology I (equipment, wet technology), High-technology II (data processing) (Masafumi Muratani) 5. High-technology (bio-informatics), Project management (Koichi Hashimoto) 6. Global drug development, and the role of Japan (Koichi Hashimoto) 7. Innovation of technology (Koichi Hashimoto) 8. Regulatory science (Kenichi Yanagi) 9. An example of translational research I (Medical device) (Hideo Tsurushima) 10. An example of translational research II (Drugs) (Takahiro Kojima)
Course Prerequisites and Advisories	
Grading Philosophy (Percentage/ Criteria/ Methodology)	Class participation (40%) and reports (60%). Grading Criteria is A+ (Superior), A (Excellent), B (Good), C (Average) and D (Failure).
Self-Directed Learning Other Than Coursework	Read textbooks and activate discussion out of classes.
Textbooks, References and Supplementary Materials	Principles and Practice of Clinical Research, John I Gallin, Frederic P Oganibene, Academic Press
Office Hours	Name: Koichi Hashimoto E-mail: koichi.hashimoto@md.tsukuba.ac.jp By appointment only
Other (i.e. Expectations on Classroom, Conduct)	

and Decorum etc.)	
Related Courses	Entrepreneurship Training I Entrepreneurship Training II Frontier Science in Drug Discovery A Frontier Science in Drug Discovery B
Keywords	Critical Path Research, Translational Research, Drug development, Medial Device