

Course Coding(科目ナンバ)	Year/Semester/Term(年度・学期)	Faculty Offering Course(時間割所属・時間割コード)	Eligible Student Year(開講年次)	Credits(単位数)	Weekday and Period(曜日・時限)
RDM7-018-83-2	2025whole year	Graduate School of Medical Sciences (20190)	1, 2, 3, 4	2	others
Course Title(Theme)(科目名(講義題目))			Instructor(s)(担当教員)		
The Theory of Clinical Research(C10Learning of The Theory of Clinical Research)			YAMAMOTO Yutaka, MATSUI Kunihiro, JONO Hirofumi, SUZUKI Makoto, MUKASA Akitake, Kanba Tomomi, IDA Satoshi, MIYAMOTO Yuji, HAYASHI Mitsuhiro		
Goals with their ratio(学修成果とその割合)					
1.Advanced expert knowledge, skill and research capability ……45% 2.Profound inter-disciplinary knowledge ……35% 4.Social leadership drive ……20%					
Type of Class(授業の形態)	Lecture				
Teaching Method(授業の方法)	PowerPoint presentation will be usually provided in the lectures. Video lectures or e-learning programs will be provided for those who are regularly absent for unavoidable reasons.				
Course Goals(授業の目的)	To comprehend necessary knowledge in order to conduct intervention studies/clinical trials				
Course Learning goals(学修目標)	【A level (A水準)】 1) To conduct scientifically rational and ethical research 2) To play a role as a project member in a large-scale or multicenter clinical study 3) To interpret research findings enough to apply into clinical practice 4) To broaden knowledge about clinical researches and standard treatments for malignancies 【C level (C水準)】 1) To comprehend scientific rationale clinical research 2) To comprehend methods to conduct clinical research 3) To comprehend development and strategies of anti-cancer drugs				
Course Outline(授業の概要)	You will learn about bases of research ethics, epidemiology, biostatistics, study design, and drug kinetics/dynamics needed for clinical trials. And also, you will learn about the biochemical characters and the treatments based on evidence of the clinical trial (EBM; evidence based medicine) in various kinds of cancers, including lung cancer, gastric cancer, colorectal cancer, liver cancer, breast cancer, urinary organ cancer and malignant brain tumor. In addition, the latest topics of the translational study and prospects of the molecular biology will be discussed.				
Details for Individual Classes(各回の授業内容)					
No.(回)	Date(月日)	Class Theme(授業テーマ)	Brief Outline of Class(内容概略)		
1		Yamamoto Yutaka, eEJ-O	Basic of clinical research 1(Clinical trials and observational studies)		
2		Yamamoto Yutaka, eEJ-O	Basic of clinical research 1(Clinical research using biomarkers)		
3		Matsui Kunihiro, eEJ-O	Details of ethical guideline for clinical research		
4		Jono Hirofumi, eEJ-O	Basics of Pharmacokinetics/Pharmacodynamics		
5		Jono Hirofumi, eEJ-O	Clinical Application of Pharmacokinetics/Pharmacodynamics		
6		Yutaka Yamamoto, eEJ-O	Design and Assessment of clinical trails		
7		Makoto Suzuki, eE-O	Clinical trials on lung cancer (1)		
8		Makoto Suzuki, eE-O	Clinical trials on lung cancer (2)		
9		Satoshi Ida, eE-O	Clinical trials on gastric cancer		
10		Yuji Miyamaoto, eE-O	Clinical trials on colorectal cancer		
11		Hiromitsu Hayashi, eE-O	Clinical trials on hepatic cell carcinoma		
12		Yutaka Yamamoto, eEJ-O	Clinical trials on breast cancer (1)		
13		Yutaka Yamamoto, eEJ-O	Clinical Trials on breast cancer (2)		
14		Tomomi Kamba, eEJ-O	Clinical Trials on urinary organ cancer		
15		Akitake Mukasa, eEJ-O	Clinical Trials on malignant brain tumor		
Estimated out-of-class study time	60 hours of self-learning (out-of-class study) is recommended in addition to 30-hours lecture (2 hours x 15 times).				
Required Textbook(テキスト)					
Reading List(参考文献)	Eanuel EJ. et al. The Oxford Textbook of Clinical Research Ethics. Oxford University Press., 2008 Breast Cancer, Molecular Genetics, Pathogenesis, and Therapeutics” edited by Bowcock, HUMANA PRESS, 2004 Cheson BD,et al. Revised recommendations of the International Working Group for Diagnosis, Standardization of Response Criteria, Treatment Outcomes, and Reporting Standards for Therapeutic Trials in Acute Myeloid Leukemia. J Clin Oncol. 2003 Dec 15;21(24):4642-9. American Society of Clinical Oncology Clinical Practice Guideline, National Comprehensive Cancer Network Clinical (NCCN) Guidelines for the Treatment of Cancer by Site, which are available on the internet.				
Enrollment Conditions(履修条件)					
Assessment Methods and Criteria(評価方法・基準)	We evaluate the attendance at a lecture, lecturing questions and answers and the lecture understanding degree about the matter which we raised to the [the aim of the class] by reports about a theme shown at being finished. Grading will be based on the student's understanding of the course subject matter. The students' understanding will be evaluated on the basis of papers and quizzes related to the topics dealt with in class to be scored from 0 to 100. Final grades will be based on the average score of the papers and quizzes as well as participation in class discussions.				

Textbook/Material Language(教科書・資料の言語)	Combination of Japanese and English
Course Based on Practical Work Experience(実務経験を 活かした授業)	Applicable (Each instructor has experiences as a primary investigator and a collaborator of clinical research projects, or a member of review boards.)