

Course Coding(科目ナンバー)	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)
RDM7-157-99-1	2025whole year	Graduate School of Medical Sciences (25250)	1, 2, 3, 4	2	others
Course Title(Theme)(科目名(講義題目))			Instructor(s)(担当教員)		
Overview of cilnical study(Overview of cilnical study (C12))			TSUJITA Kenichi, SAKAGAMI Takuro, YAMAZAKI Hajime, KAWAGUCHI Takayoshi, SANUKI Tetsuji, MATSUI Kunihiko, NAKAMURA Taishi, MIYASHITA Azusa, Morinaga Jiyun, YAMASAKI Akira, NOSAKA Kisato, NAGAOKA Katsuya		
Goals with their ratio(学修成果とその割合)					
1.Advanced expert knowledge, skill and research capability ……80% 2.Profound inter-disciplinary knowledge ……10% 3.Global perspective and ability to take initiative action ……5% 4.Social leadership drive ……5%					
Type of Class(授業の形態)	Lecture				
Teaching Method(授業の方法)	Face-to-face or e-learning lectures using handouts.				
Course Goals(授業の目的)	The purpose of this lecture is to provide young researchers who are about to start clinical research with the basic knowledge necessary to plan and conduct their research.				
Course Learning goals(学修目標)	【A level (A水準)】 Acquire sufficient knowledge to plan and conduct clinical research, in addition to concepts related to the framework of observational and interventional research, research ethics, statistics, regulations, practices, big data construction and utilization, intellectual property, etc. 【C level (C水準)】 Acquire essential knowledge to plan and conduct clinical research, in addition to concepts related to the framework of observational and interventional research, research ethics, statistics, regulations, practices, big data construction and utilization, intellectual property, etc.				
Course Outline(授業の概要)	The course provides an overview of observational and intervention research, research ethics, statistical concepts, study design, regulations and practices, and big data construction and utilization, as well as the essence of knowledge about intellectual property.				
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		SAKAGAMI Takuro, [eJ-O]	Introduction to clinical research: Translational research(Active Learning)		
2		YAMASAKI Akira, [eJ-O]	Research Ethics: Protecting participants in clinical research		
3		MORINAGA Jun, [eJ-O]	Statistical principles in clinical research		
4		MORINAGA Jun, [eJ-O]	Introduction of study design in clinical research		
5		MIYASHITA Azusa, [eJ-O]	Understanding guidelines and laws in clinical research		
6		MIYASHITA Azusa, MORINAGA Jun, [eJ-O]	Introduction of protocol writing in clinical research		
7		MATSUI Kunihiko, [eJ-O]	Promotion and practice of observational study		
8		TSUJITA Kenichi, [eJ-O]	Promotion and practice of interventional study		
9		NAKAMURA Taishi, [eJ-O]	Construction and application of medical big data		
10		NOSAKA Kisato, [eJ-O]	Clinical Trial Regulations and Project Management		
11	12/11	Thu. 4th period. SANUKI Tetsuji, [eJ-L]	Management of medical device development		
12	12/18	NAGAOKA Katsuya, [eJ-L]	Potential for AI Applications in Clinical Research		
13		KAWAGUCHI Takayoshi, [eJ-O]	Importance of intellectual property in clinical development		
14	01/15	Thu. 3th period. YAMAZAKI Hajime, [eJ-L]	Practice of study design in clinical research 1 (Active Learning)		
15	01/15	Thu. 4th period. YAMAZAKI Hajime, [eJ-L]	Practice of study design in clinical research 2 (Active Learning)		
Estimated out-of-class study time					
Required Textbook(テキスト)		Textbooks are not specified.			
Reading List(参考文献)		Provided in the lectures.			
Enrollment Conditions(履修条件)		No prerequisite.			
Assessment Methods and Criteria(評価方法・基準)		The level of understanding of the lectures will be evaluated by examining the reports and scores in quizzes related to the lectures.			
Language Used in Instruction(使用言語)		Japanese			
Textbook/Material Language(教科書・資料の言語)		Japanese			
Course Based on Practical Work Experience(実務経験)		Applicable			