		emester/Ter 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 2023		vhole year	Graduate School of Medical Sciences (25250)	1		2	others			
		Co	urse Title(Th	neme)(科目名(講義題目))			Instructor(s)(担当教員)		
	Overvi	ew of cli	lilnical study(Overview of clilnical study(C12))			TANAKA Yasuhito, YAMASAKI Akira, MORINAGA Jun, MIYASHITA Azusa, MATSUI Kunihiko, TSUJITA Kenichi, NAKAMURA Taishi, TODAKA Koji, UCHIYAMA Makiko, SANUKI Tetsuji, KAWAGUCHI Takayoshi, YAMAZAKI Hajime				
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)		Bri	ef Outline of Cl	ass(内容概略)		
1	10/05		Thu. 4th pe	riod. TANAKA Yasuhito, 【eJ-L】	Introduction to clinical research: Translational research					
2	10/12		Thu. 4th pe	riod. YAMASAKI Akira, 【eJ-L】	Research Ethics: Protecting participants in clinical research					
3			MORINAGA Jun, [eJ-0] Stati			atistical principles in clinical research				
4			MORINAGA	NAGA Jun, [eJ-0] Introduction			of study design in clinical research			
5	11/02		Thu. 4th period. MIYASHITA Azusa, [eJ-L] Und			nderstanding guidelines and laws in clinical research				
6	6		MIYASHITA Azusa, MORINAGA Jun, [eJ-0] Introd			oduction of protocol writing in clinical research				
7	7 11/16		Thu. 4th period. MATSUI Kunihiko, 【eJ-L】 Pro			Promotion and practice of observational study				
8	3 11/30		Thu. 4th period. TSUJITA Kenichi, 【eJ-L】			Promotion and practice of interventional study				
9	9 12/07		Thu. 4th period. NAKAMURA Taishi, 【eJ-L】 Cor			Construction and application of medical big data				
10	10		TODAKA Koji, [eJ-0]			Regulatory science				
11	11		UCHIYAMA	JCHIYAMA Makiko, [eJ-0] Mai			anagement of clinical study			
12			SANUKI Tetsuji, 【eJ-0】 Ma			lanagement of medical device development				
13	01/1	8	Thu. 4th pe	riod. KAWAGUCHI Takayoshi, 【eJ-L】	Impo deve	rtance of intellectual property in clinical lopment				
14	01/2	5	Thu. 4th pe	riod. YAMAZAKI Hajime, 【eJ-L】	Practice of study		y design in clinical research 1			
15	15 02/01		Thu. 4th period. YAMAZAKI Hajime, 【eJ-L】 Pra			actice of study design in clinical research 2				
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 を活かした授業)			Not applicable							