

Course title <English>	臨床試験 Clinical Trial		Affiliated department, Job title,Name	Graduate School of Medicine Program-Specific Professor,TANAKA SHIROU Graduate School of Medicine Professor,FURUKAWA TOSHIKI Graduate School of Medicine Program-Specific Assistant Professor,OOMAE KATSUHIRO Graduate School of Medicine Senior Lecturer,NISHIYAMA CHIKA 京都府立医科大学 教授 TERAMUKAI SATOSHI 名古屋医療センター臨床疫学研究室 室長 SAITO AKIKO		
Target year	Professional degree students	Number of credits	2	Course offered year/period	2018/First semester	
Day/period	Wed.5	Class style	Lecture	Language	Japanese and English	
[Outline and Purpose of the Course]						
This course consists of lectures on methodology of clinical trials in accordance with Chapter 3, 5, 6, 9, 10 and 12 to 15 of “ Clinical Trials: A Practical Approach ” . In addition, 3 lecturers who experienced in investigator-initiated clinical trials in cardiovascular disease, cancer, and translational research areas provide lectures on the practical aspects of clinical trials based on their experience. This course also includes a workshop of developing study protocols of hypothetical clinical trials with small-sized groups. MCR required, CB required, MPH elective.						
[Course Goals]						
To understand methodology of clinical trials To understand contents of study protocol and learn how to develop a study protocol through a workshop of protocol development						
[Course Schedule and Contents]						
April 11 Overview (Furukawa) April 18 Organization and Planning (Tanaka) April 25 Experience in Education Intervention Trials in Cardiovascular Disease (Nishiyama) May 9 Issues in Conducting Cancer Clinical Trials and Their Solutions (Saito) May 16 Cancer Phase I, I, III Trials (Tanaka) May 23 Endpoints, Randomization and Blinding May 30 Publication and Interpretation of Findings (Furukawa) June 6 Statistical Consideration in Protocol Development (Teramukai) June 13 Statistical analysis 1 (Tanaka) June 20 Statistical analysis 2 (Tanaka) June 27 Workshop (protocol development, Tanaka, Aida, Imai) July 4 Workshop (protocol development, Tanaka, Aida, Imai) July 11 Workshop (protocol development, Tanaka, Aida, Imai) July 18 Workshop (protocol development, Tanaka, Aida, Imai) July 25 Workshop (presentation, Furukawa, Tanaka, Aida, Imai)						
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臨床試験(2)

[Class requirement]

None

[Method, Point of view, and Attainment levels of Evaluation]

Attendance 50%, Report 50%

[Textbook]

Stuart J. Pocock 『Clinical Trials: A Practical Approach』 (Wiley)

A copy of the textbook will be provided.

[Reference books, etc.]

(Reference books)

[Regarding studies out of class (preparation and review)]

Please read the textbook "Clinical Trials: A Practical Approach".

(Others (office hour, etc.))

*Please visit KULASIS to find out about office hours.