### Course title
Clinical Trial

### Affiliated department, Job title, Name
- Graduate School of Medicine Program-Specific Professor, TANAKA SHIROU
- Graduate School of Medicine Professor, FURUKAWA TOSHIAKI
- Graduate School of Medicine Senior Lecturer, NISHIYAMA CHIKA
- Program-Specific Assistant Professor, SATO IZUMI
- TERAMUKAI SATOSHI
- SAITO AKIKO

### Target year
Professional degree students

### Number of credits
2

### Course offered year/period
2017/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, 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 12 Overview (Furukawa)
- April 19 Experience in Education Intervention Trials in Cardiovascular Disease (Nishiyama)
- April 26 Issues in Conducting Cancer Clinical Trials and Their Solutions (Saito)
- May 10 Statistical Consideration in Protocol Development (Teramukai)
- May 17 Organization and Planning, Method of Randomization, Blinding and Placebos (Tanaka)
- May 24 The Size of a Clinical Trial (Tanaka)
- May 31 Monitoring Trial Progress; Protocol deviations (Tanaka)
- June 7 Statistical analysis 1 (Tanaka)
- June 14 Publication and Interpretation of Findings (Furukawa)
- June 21 Statistical analysis 1 (Tanaka)
- June 28 Workshop (protocol development)
- July 5 Workshop (protocol development)
- July 12 Workshop (protocol development)
- July 19 Workshop (protocol development)
- July 26 Workshop (presentation)

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[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.*