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|--|------------------------|------------------------------|--|--|-----------------|-----------------------------------|
| Course title <English> | 臨床試験 Clinical Trial | | Affiliated department, Job title,Name | Graduate School of Medicine Senior Lecturer,TANAKA SHIROU Graduate School of Medicine Professor,FURUKAWA TOSHIAKI Graduate School of Medicine Senior Lecturer,NISHIYAMA CHIKA Graduate School of Medicine Program-Specific Assistant Professor,SATO IZUMI 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 | | |
| | Grade allotted | Professional degree students | | Number of credits | 2 | Course offered year/period |
| 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 8 Overview (Furukawa) April 15 Experience in Education Intervention Trials in Cardiovascular Disease (Nishiyama) April 22 Issues in Conducting Cancer Clinical Trials and Their Solutions (Saito) May 13 Statistical Consideration in Protocol Development (Teramukai) May 20 Organization and Planning, Method of Randomization, Blinding and Placebos (Tanaka) May 27 The Size of a Clinical Trial (Tanaka) June 3 Monitoring Trial Progress; Protocol deviations (Tanaka) June 10 Statistical analysis 1 (Tanaka) June 17 Publication and Interpretation of Findings (Furukawa) June 24 Statistical analysis 1 (Tanaka) June 1 Workshop (protocol development) June 8 Workshop (protocol development) June 15 Workshop (protocol development) June 22 Workshop (protocol development) June 29 Workshop (presentation) | | | | | | |
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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.