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| Course Name | Methods in Clinical Trials |
| Course Number | OATHF32 |
| Credits | 1.0 Credits |
| Adaptation years | 1, 2 Year |
| Class hold days | FallAB Tue7,8 |
| Instructor | Yukiko Wagatsuma, Masahiko Goshō |
| Overview | Clinical trial is a comparison test of a medical treatment, versus a placebo, or the standard medical treatment for a patient's condition. Good Clinical Practice (GCP) guidelines include the standards on how clinical trials should be conducted, define the roles and responsibilities of clinical trial sponsors, clinical research investigators and monitors. The aim of this course is to learn about the outline of clinical trials and GCP. |
| Remarks | Lectures are conducted in English. face-to-face (partially online) |
| Course Type | lectures |
| Relation to Degree | Generic competence: Knowledge application |
| Program Competences | Specific competence: Public health core 1: Epidemiology |
| Course Objectives (Learning Outcomes) | <ol style="list-style-type: none"> Students will be able explain about the steps involved in clinical trials. Students will understand ethical guidelines related to clinical trials, and be ready to develop a protocol of their own research. Students will understand the issues involved during the implementation of clinical trials. Students can discuss about the pros and cons of selected methods. |
| Class Schedule | <p>The course is offered by face-to-face and online teaching.</p> <ol style="list-style-type: none"> Nov 14, Class 7・8; Yukiko WAGATSUMA; Research ethics Nov 21, Class 7・8; Yukiko WAGATSUMA; GCP Nov 28, Class 7・8; Yukiko WAGATSUMA; Protocol development Dec 5, Class 7・8; Masahiko GOSHŌ; Biostatistical issues Dec 12, Class 7・8; Masafumi OKADA; Data management Dec 19, Class 7・8; Mariko DOI; Quality assurance |
| Course Prerequisites | None |
| Grading Philosophy | Evaluated by term report. |
| Course Hours Breakdown and Out-of- Class Learning | All classes are conducted in lectures. Students should prepare for the classes by reading relevant chapters of the textbook. |
| Textbooks, References, and Supplementary Materials | 1. Lawrence M. Friedman, Curt D. Furberg and David L. DeMets, Fundamentals of Clinical Trials, 4th Edition, Springer, 2010. |
| Office Hours and Contact Information | Yukiko Wagatsuma 随時、メールにて事前連絡 ywagats at md.tsukuba.ac.jp |
| Other (Behavioral expectations and points to note for students during | |

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| coursework) | |
| Relation to Other Courses | |
| Teaching Fellow and/or Teaching Assistant | |
| Course Keywords | Clinical trial, research ethics, GCP, quality assurance, data analysis, data management, protocol development. |