

Lecture Series “Riron”: C10 The Theory of Clinical Research

Subject Code 2 0 1 9 0

(Elective: 2 credits)

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【Objectives】

In Lecture Series, C10 The Theory of Clinical Research, you learn the theory of the clinical research that assumed bioethics a background systematically and learn treatment to be based on a characteristic of the biology, as evidence based medicine, especially in lung cancer and breast cancer. Furthermore, you learn the basics for new treatments based on clinical translational researches, the development of new drugs based on the data of clinical trials, pharmacokinetics and those ethics.

【Content Description】

These lectures consist as follows;

- 1) Bioethics; the clinical research that assumed bioethics a background for the history of the study theory, a problem of the ethic issues specialized in the methodology of the clinical study, a study participant needing special consideration, the ethic guideline attentive reading of the clinical study, consideration about the social responsibility of the researcher.
- 2) Lung cancer has most frequent mortality rate in male cancer. You learn the epidemiology, biochemical characters, clinical pharmacokinetics and the treatments based on evidence of the clinical trials, EBM. In addition, the latest topics of the translational study and prospects of the molecular biology will be discussed.
- 3) Breast cancer is a most common cancer in women, and has a unique character, which is hormone dependency. The epidemiology, diagnostic procedure, surgical technique, hormonal therapy, chemotherapy and molecular targeting therapy will be discussed. Furthermore, new drugs and treatment strategies will also be addressed.

【Keywords】

clinical research, life ethics, ethic guideline, lung cancer, breast cancer, EBM, chemotherapy, molecular target therapy, pharmacokinetics, EBM, clinical trial, a translational study, individualized treatment

【Class Style】 PowerPoint will be usually used in the lectures. Video lectures or e-learning programs may be considered for those who are regularly absent for unavoidable reasons.

【Textbooks】

“BMA Ethics Department Medical Ethics Today” The BMA's handbook of ethics and law, BMJ Books, 2004, 489-534 (Chapter 14: Research and Innovative treatment). Timothy F. Murphy Case Studies in Biomedical Research Ethics. The MIT Press, 2004.

“Breast Cancer, Molecular Genetics, Pathogenesis, and Therapeutics” edited by Bowcock, HUMANA PRESS, 2004

【Recommended Readings】 Not specified.

【Office Hour】 If you have any questions on topics or schedule of the classes, please contact the instructors listed above by e-mail.

【Evaluation for Grades and Credits】 Grading will be based on active class participation, paper summaries, or the final report.

The sessions marked with “e” are under preparation of e-learning contents. In some cases, the session that is not marked with “e” will be done by utilizing e-learning system, as soon as the e-learning contents are ready for use. Therefore, you must check the updated syllabus cited on the home page of the Graduate School of Medical Sciences, Kumamoto University to check the current status of the session before you take a session. If you cannot obtain enough information from the home page, please make contact with the instructors of the sessions. There are two types of e-learning, those marked with “eL” and “eO”. The session marked with “eL” will be done as both a traditional face to face lecture style and e-learning (for the students who cannot attend the session). On the other hand, the session marked with “eO” will be done only as e-learning and no face to face lecture will be given. To learn how to use e-learning system, please see the section explaining about the e-learning system in this syllabus.

【Lecture Schedule】

Session	Date & time	Instructors	Topics
1 .	Oct 16 (Fri) 6th period	Atushi Asai	History of bioethics for clinical research
2 .	Oct 19 (Mon) 5th period	Atushi Asai	Ethical issues based on methodology of clinical research
3 .	Oct 26 (Mon) 5th period	Atushi Asai	For participants needing special consideration
4 .	Nov 2 (Mon) 5th period	Atushi Asai	Details of bioethical guideline for clinical trials
5 .	Nov 9 (Mon) 5th period	Atushi Asai	Social responsibility for clinical researcher
6 .	Nov 16 (Mon) 5th period	Ji-ichiro Sasaki	Epidemiology and Prevention for lung cancer
7 .	Nov 25 (Wed) 5th period	Ji-ichiro Sasaki	Histological characteristics of lung cancer
8 .	Nov 30 (Mon) 5th period	Ji-ichiro Sasaki	Chemotherapy for lung cancer and EBM
9 .	Dec 7 (Mon) 5th period	Ji-ichiro Sasaki	Translational research for lung cancer
1 0 .	Dec 14 (Mon) 5th period	Ji-ichiro Sasaki	Clinical research of therapeutic strategy for LC
1 1 .	Dec 21 (Mon) 5th period	Hirota Iwase	Epidemiology and character of breast cancer
1 2 .	Jan 4 (Mon) 5th period	Hirota Iwase	Diagnosis and surgery for breast cancer
1 3 .	Jan 15 (Fri) 5th period	Hirota Iwase	Design, evaluation of clinical trials
1 4 .	Jan 18 (Mon) 5th period	Hirota Iwase	Endocrine therapy for breast cancer
1 5 .	Jan 25 (Mon) 5th period	Hirota Iwase	Chemotherapy and target therapy for breast cancer