Course title <English>	医薬品の開発と評価 Drug Development, Evaluation and Regulatory Sciences	Affiliated department, Job title,Name	Graduate School of Medicine Professor,KAWAKAMI, KOJI

Target year	Professional degree students	Number of credits	1	Course offered year/period	2018/Intensive, Second semester

Day/period	Intensive	Class style	Lecture	Language	Japanese and English

[Outline and Purpose of the Course]

Director and Instructors:
(Director) Koji Kawakami (Professor, Pharmacoepidemiology),Hiromitsu Shirasawa (MSD, Japan),
Ikuo Horii (Cambridge Univ.),
MasayoshiMurakami(Foundation for Biomedical Reserch and Innovatuion),Hisashi Urushihara (Keio Univ.),
Yoshie Onishi(CreativCeutical), Haruka Yoshimura(MOF)

The efficacy and safety of the drug, biologics, and medical devices are evaluated through the drug development process involving preclinical and clinical studies,manufacturing, and post-marketing surveillance. Also, cost/benefit consideration through the comparative effective research is necessary. Fundamental considerations of these issues along with research examples will be discussed.

[Course Goals]

To understand idea of the development, evaluation, cost/benefit of medicinal products.

[Course Schedule and Contents]

November 21 Regulatory affairs in the globalwide pharmaceutical company (Shirasawa)
November 28 Drug development and toxicity/safety (Horii)
December 5 Tanslational reserch and industrializatons(Murakami)
December 12 Medical real world data and Medicine evaluation(Kawakami)
December 19 Postmarketing surveillance (Urushihara)
Dcember 26 Pharmacoeconomics and value-based drug pricing (Onishi)
January 9 Finance of Japan and healthcare(Yoshimura)
January 16 Sight visiting of Kobe medical cluster

[Class requirement]

You must take this course along with the course H109 “Drug policy and regulation” otherwise the entire grasp of the drug research, development, and regulations will not be achieved.

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

Participation (50%) and report (50%)

[Textbook]

Suggested reading:
Hartzema, A.C. et al., ed. Pharmacoepidemiology: An Introduction 3rd ed., Harvey Whitney. 1998.
Saeko Yasuo et al. Invitation to new drug development. Kyoritsu Press, 2006 (Japanese).
Koji Kawakami (ed.) The Beginner’s guidance to the clinical research and development. Medical Do, 2010

Continue to 医薬品の開発と評価(2)↓↓↓

医薬品の開発と評価(2)

(Japanese).

[Reference books, etc.]

（Reference books）

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

Preparation in advance and review after lecture

（Others (office hour, etc.)）

Koji Kawakami （3F, Bldg G） appointment required by email.
e-mail: kawakami.koji.4e@kyoto-u.ac.jp
intermediate

*Please visit KULASIS to find out about office hours.