Research Center for Medical Sciences
Division of Clinical Pharmacology and Therapeutics

Shigeru Kageyama, *Professor and Director* Akihiro Ohnishi, *Professor*

General Summary

The Division of Clinical Pharmacology and Therapeutics was established in July 1995. The aim of the division is to investigate drug treatment, mainly in the area of internal medicine, whereas other departments of clinical pharmacology in Japan focus on registration trials, particularly phase I trials. Because a clinical laboratory where we had performed many human pharmacological studies became unavailable in 2003, we shifted our research from human studies to multicenter clinical trials and pharmacoepidemiological studies.

Research Activities

So far, we have performed a large-scale pharmacoepidemiological study on the safety of statins. It took a quite a long time to complete it, therefore, we organized a research group comprising academic and industrial organizations (Japanese Society for Pharmacoepidemiology, Japanese Society of Clinical Pharmacology and Therapeutics, Japan Association for Medical Informatics, Japan Society of Clinical Trials and Research, Federation of Pharmaceutical Manufacturer's Associations of Japan, Pharmaceutical Research and Manufacturers of America, and European Federation of Pharmaceutical Industries and Associations Japan) to make postmarketing studies more efficient by utilizing the Standardized Structured Medical-record Information eXchange (SS-MIX). The SS-MIX system was started in 2006 as a project supported by the Ministry of Health, Labour and Welfare for promoting the exchange of standardized medical information. The SS-MIX system will increase the efficiency of pharmacoepidemiological studies by identifying "new users" who started the drug after some period of nonuse. The "new user" design is often essential for unbiased results. In the 3 Jikei University Hospitals (Katsushika Medical Center, Daisan Hospital, and Kashiwa Hospital) where electronic medical record systems have already installed we are going to collect prescription and medical test data to make diabetic disease registries. We are planning to broaden disease registries to various diseases.

To raise the literacy of clinical trials among researchers we held "Clinical Trial Seminar" 2 times this year. The themes were as follows: "Systems for improving the quality of clinical trials." (May 2016), "Basic knowledge on intellectual property for researchers." (March 2017).
An administrative office for registration trials was established in the hospital in February 1999, and the system for registration trials in the hospital has been reformed to meet the demands of the new good clinical practice guidelines. Ten clinical research coordinators

(CRCs) now facilitate clinical trials of which 2 CRCs have mainly been involved in monitoring. The CRCs have started to help with both registration trials and investigator-initiated trials. The CRCs have been introduced into all registration trials since 2004; the quality and speed of these trials were much improved.
As the introduction of CRCs into investigator-initiated trials increased, we invited CRCs from site management organizations to supplement CRCs involved in registration trials.

Publications

Odawara M[1], Kawamori R[2], Tajima N, Iwamoto Y[3], Kageyama S, Yodo Y[4], Ueki F[4], Hotta N[5] ([1]Tokyo Medical Univ, [2]Juntendo Univ Grad Sch Med, [3]Asahi Life Foundation, [4]Sumitomo Dainippon Pharma, [5]Chubu Rosai Hosp). Long-term treatment study of global standard dose metformin in Japanese patients with type 2 diabetes mellitus. *Diabetology Int.* 2017; **8:** 286-95. Epub 2017 Feb 24.