

Research Center for Medical Sciences

Division of Clinical Pharmacology and Therapeutics

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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 some 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

We have performed a large-scale pharmacoepidemiological study of the safety of statins. Because the study took a long time to complete, 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 Manufacturers' 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 to promote the exchange of standardized medical information. The SS-MIX system will increase the efficiency of pharmacoepidemiological studies by identifying "new users" who have started using the drug after a period of nonuse. The "new user" design is often essential for obtaining unbiased results. In the 3 hospitals affiliated with The Jikei University (Katsushika Medical Center, Daisan Hospital, and Kashiwa Hospital), where electronic medical record systems have already been installed, we collected prescription and medical test data. As of January 2016, prescription and medical test data have been incorporated into SS-MIX. In January 2018 data from The Jikei University Hospital was finally incorporated into SS-MIX storage, a large scale data set of various diseases from all 4 hospitals became available. We introduced this system to Department of Dermatology and to all the divisions of Department of Internal Medicine. Several studies using the SS-MIX system are in progress.

To raise the literacy of clinical trials among researchers, we held the "Clinical Trial Seminar" in October 2018. The theme was "Big Data in Cardiovascular Diseases and Clinical Innovation Network."

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. Clinical trials are now facilitated by 10 clinical research coordinators (CRCs), of whom 2 have also 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 have been much improved.

Investigator-initiated registration trials which were managed by other medical institutions have been conducted so far. Since 2017 an investigator-initiated registration trial which was designed and planned by an investigator of The Jikei University has been conducted. In this trial data management was outsourced to a contract research organization.

We have also supported investigator-initiated clinical trials in collaboration with the Clinical Research Support Center. Details are described in the Clinical Research Support Center section of this annual review.