

 **Clinical Research Supporting Business** 

Importance of clinical researches to optimize the treatment strategies has recently been recognized. A rather large organization is required for a clinical research. Human resources needed include the employees for data acquisition, data input, data cleaning and data analysis. What system is appropriate for the construction and the maintenance of such an organization?

The system lead by a pharmaceutical company is considered to be inappropriate. This is because of a possible bias toward the benefit of the own company. On the other hand, relying on the academy to maintain such a system is not practical. StaGen has sufficient achievements in the support business for clinical research. Naoyuki Kamatani, MD, PhD, the chairman of StaGen Co. Ltd had supervised, for 10 years, a cohort study for rheumatoid arthritis, “IORRA” in which about 5,000 rheumatoid arthritis patients had been enrolled when he was the director of Institute of Rheumatology, Tokyo Women’s Medical University. In addition, StaGen is now in charge of the management of DIACET in Diabetes Center, Tokyo Women’s Medical University (Director Yasuko Uchigata, MD) in which about 10,000 diabetes patients have been enrolled. Furthermore, in 2012, StaGen Co. Ltd performed the study “Efficacy and safety of methotrexate (MTX) at the doses over 8 mg/week: Analysis of the data from three separate Japanese cohort studies, IORRA, REAL and Ninja” answering to the request by Japanese College of Rheumatology. This report was submitted to Ministry of Health, Labour and Welfare of Japan by Japanese College of Rheumatology to get the approval from the ministry to use MTX over 8 mg/week up to 16 mg/week. As a result, the use of MTX at the doses over 8 mg/week up to 16 mg/week was approved by the government. StaGen has also analyzed the data from post-marketing surveillance (PMS) studies from two pharmaceutical companies.

We wait for inquires from pharmaceutical companies, medical societies, foundations and clinical research groups.