

Support for Clinical Trials Including Genomic Information

Because of the development of advanced technologies to obtain genomic information and the establishment of ethical guidelines for genomic research, more and more clinical trials include genomic information to make the development of new drugs more efficient and safer. StaGen Co. Ltd has a lot of experiences in analyzing genomic data in clinical trials.

Specialists with plenty of experiences in medicine, statistics and genetics perform PGx analysis in clinical trials.

We support the entire process of clinical trials beginning from estimation of necessary sample sizes by the power analysis based on statistical genetics followed by the designing of the statistical analysis, designing of the figures and tables and designing of the documents to explain the genomic analysis in the trial as well as the form of informed consent.

We provide analysis based on reliability criteria

We provide high-quality results of analyses performed by talented specialists with more than 10-year experiences as the principle investigators and with sufficient knowledge concerning ethics, laws, enforcement order and enforcement regulations concerning PGx in clinical trials. We are experts of SAS, S-PLUS and R programmings. On the other hand, we provide high-quality results of the analyses for GWAS data that cannot be analyzed by SAS or S-PLUS.

We perform in-house training of employees

We hold in-house seminar every week and expand our technologies and knowledge of statistical genetics. Our employees attend not only scientific meetings but also seminars for making CTD documents and CSV technology.

We have sufficient achievements in clinical trials using PGx

We have experiences in analyzing genomic information in all the stages from Phase I to Phase IV. Especially, we contributed to the approval by Ministry of Health, Labour and Welfare of Japan to use MTX over 8 mg/week up to 16 mg/week for rheumatoid arthritis.

We support the analyses of the data from clinical trial in which JPDSC data are used

We support PGx studies in clinical trials in which GWAS and HLA data from 3,000 individuals are used that were collected by Japan PGx data Science Consortium (JPDSC) consisting of 6 Japanese pharmaceutical companies.