CSS

TO SUPPORT PEOPLE'S LIFE

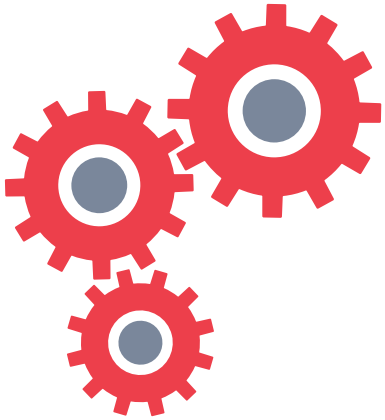
ACT NOW, THINK TOGETHER
CSS PRIDE

Since 2004, Clinical Study Support (CSS), inc. has supported clinical research in real-world settings and patient-reported outcomes questionnaire development. We have strong expertise in supporting professional experts from local to global levels through English communication.

CONCEPT

WHO WE ARE

“TO SUPPORT PEOPLE’S LIFE” is our corporate philosophy



Over the past years, a variety of treatments have become available, but none of them is perfect. People ultimately choose their own treatments from among various confusing options. Treatment selection is a crucial decision, which can affect one’s entire life. In extreme cases, such as life-threatening diseases, selecting treatment is equivalent to making choices that affect remaining life span.

Our philosophy, “**TO SUPPORT PEOPLE'S LIFE**”, aims to create a healthcare environment which enables people to make informed decisions and optimize their treatment selection. Mostly, treatment is based on the information provided by clinical research. We strive to help them make their own decisions by providing reliable information obtained from ethical and scientific clinical research.

We focus on the Real-world phase in Japan, but why?

We mainly focus on the post-marketing Real-world (RW) phase. The development phase is really important for drug approval, but it mainly provides the information on whether a given medication is better than a placebo or the standard medication. To optimize its value and safe use, we need to continuously add to new information, for instance, to determine which patients may benefit more or less in efficacy and safety using clinical use data.

Mostly, RW research is exploratory and observational. Compared to the development phase, although data collection is more flexible and less costly, statistical analysis and interpretation are more complex due to inherent biases and confounding. To obtain useful and reliable information for therapeutic use, both theoretical and practical expertise are required.

Japan is the third largest drug market in the world. Due to the extensive volume of RW data, when properly analyzed and interpreted, RW insights from Japan-based clinical research can play an important role in better understanding medications not only for the Japanese but also for people globally.

WHAT WE DO

Services

As clinical research professionals, we support the whole process of clinical research, such as clinical trials, epidemiological observational studies and surveys, through consultation. We have strong expertise in supporting professional experts from local to global levels through English communication.

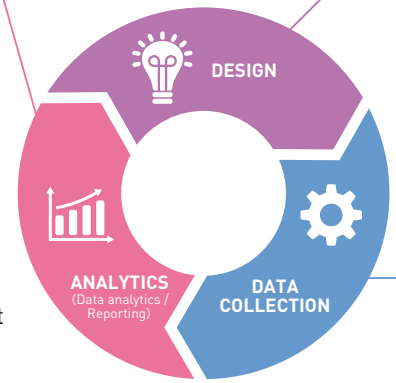
Statistical analysis & Medical writing

Statistical analysis

- Analysis proposal & consultation
- Statistical analysis plan development
- Implementation of analysis
- Statistical analysis report development

Medical writing

- Manuscript development support
- Review comment response and manuscript revision
- Conference preparation support (poster & slides)



Proposal & Plan

- Study design proposal
- Sample size estimation
- Protocol development
- Study implementation planning
- Preparation for ethical committees

Study implementation & Data management

- Data management planning & execution
- Central monitoring
- Study site management
- Study office

Target phase

Since starting the company in 2004, we have mainly focused on the post-marketing Real-world (RW) phase. Our service scope is the RW-related research, such as database studies, questionnaire development and pharmacoeconomics.

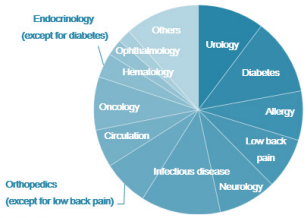
WHAT MAKES CSS DIFFERENT

Years of expertise in research and publication since 2004

- Supports various types of “Real-world (RW)”-related research. We work with a wide range of clients from academic to commercial and from domestic to international
- Helps develop a strategic design & plan for publication with high expertise in English medical writing. We have achieved 150+ publications with a 100 acceptance rate
- Has strong expertise in cross-cultural adaptation and psychometric validation of patient-reported outcomes (PRO) questionnaires

Number of projects contracted

Contracts by area



550+ Projects

100% Acceptance rate

150+ Publications

Team features and principles as professionals and solution-providers

- Clinical research planning, analysis and writing experts with research-related PhDs and MSs (biological and medical science, especially, epidemiology, applied statistics, medical statistics, economy and sociology)
- Working with clients on challenging proposals to meet both budget and research scope
- Constant training and platform improvement to expand our solution scope
- Logical and critical thinking based process leading to a high publication acceptance rate
- Data visualization to enhance focused communication based on a shared vision

Our project and publication lists can be found at our website: http://jp-css.com

RW Database studies

We support development of evidence in Real-world (RW) settings using patient RW data, such as electronic medical records and administrative claims databases.

- We suggest the proper epidemiologic and analytic methods.
- We support the project throughout the protocol development, statistical analysis, and publication.
- We are able to communicate both in English and Japanese.

10+
Projects
Per year

We provide the following services for studies using databases.

- Suggestion of analytic plan
- Development of a protocol and a statistical analysis plan
- Conduct of statistical analysis
- Development of research manuscript and publication support.

Examples of real world database study include

- Understanding of treatment patterns
- Understanding of patient profiles for a disease or a treatment
- Association between a treatment and outcomes
- Drug post-marketing surveillance program

Our experience in database analysis in understanding disease-specific treatment patterns allows more effective use of medicine that will enhance pharma's commercial engagement.

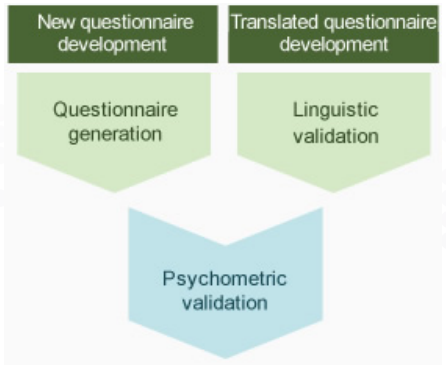
PRO questionnaire development

We support development of questionnaires to measure health-related patient-reported outcomes (PRO); for instance, quality of life and patient satisfaction.

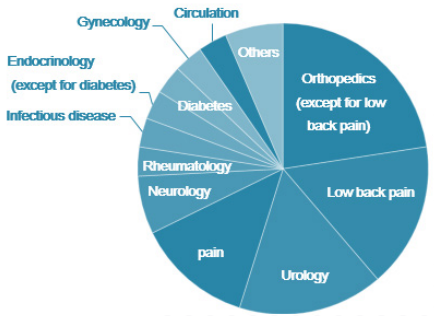
Our support includes

- Development of new questionnaires
- Translating existing English questionnaires into Japanese to include linguistic validation (cross-cultural adaptation)
- Psychometric validation (validity, reliability and responsiveness assessments) of the developed questionnaires

We have extensive experience of PRO questionnaire development with 30+ projects.



Questionnaire development by area



Pharmacoeconomics

We support an economic evaluation of pharmaceuticals (health technology assessment of drugs), including cost-effectiveness analysis and cost-utility analysis. Generally, in the pharmacoeconomic assessment, economic models are developed applying decision trees, Markov models or other appropriate techniques, based on existing data and literature review. For instance, we can provide the following services for pharmacoeconomic assessment

- Research proposal and protocol development through consultation
- Systematic literature reviewing, including quality appraisal and data extraction, and meta-analysis when necessary
- Economic model development and validation
- Reporting of results and interpretation
- Medical writing and publication support