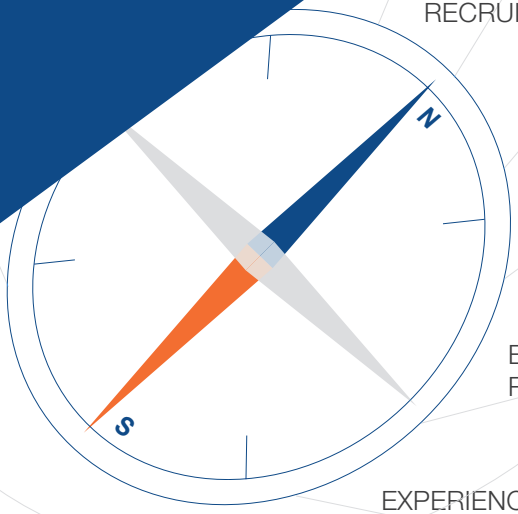
THE WORLD OVER,
CLINICAL TRIALS IN

ALZHEIMER'S

DISEASE
HAVE ONE NAME
- QPS



SPEEDY PATIENT
RECRUITMENT

PROFICIENT
REGULATORY
AFFAIRS

EFFICIENT PATIENT
RETENTION

EXPERIENCED
INVESTIGATORS

QPS
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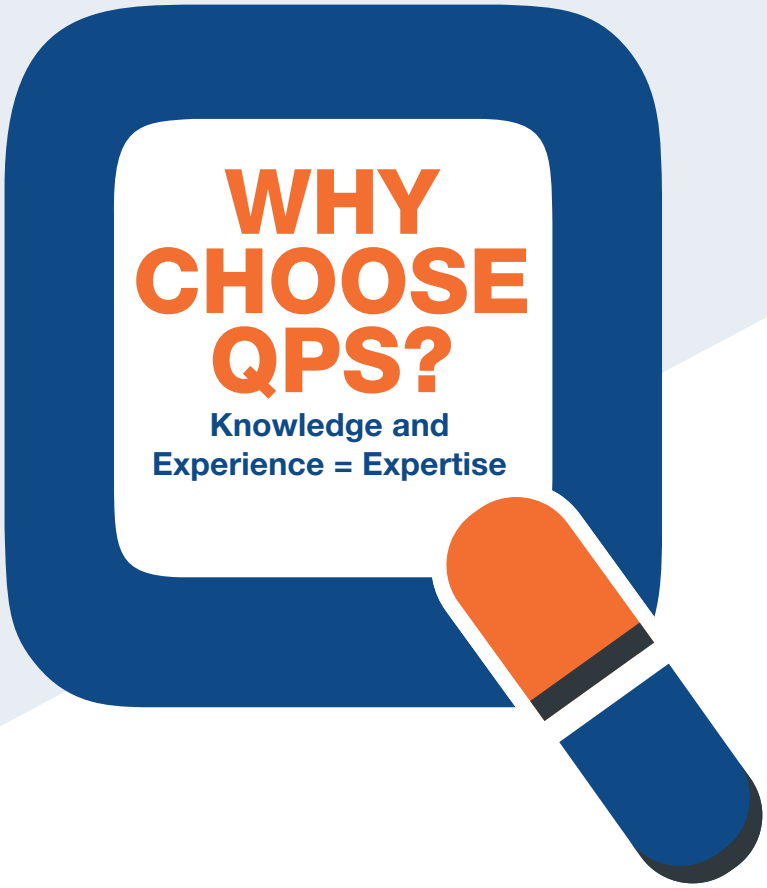
ALZHEIMER'S DISEASE: A GLOBAL FOOTPRINT

The increasing worldwide incidence of Alzheimer's disease (AD) calls for conscientious clinical trials of new treatments, particularly those effective in early intervention, and necessitates the development of reliable diagnostics for very mild disease stages, as well as adaptive study designs.

- Nearly 35.6 million people currently suffer from AD, worldwide.
- WHO projects this number will double by 2030 (65.7 million) and more than triple by 2050 (115.4 million).
- More than 58% of those affected by dementia live in low and middle-income countries. This percentage is expected to rise to more than 70% by 2050.

CURRENT CHALLENGES

Conducting clinical trials on Alzheimer's disease (AD) presents particular challenges because of the nature of the illness and the patient population. The lack of established biomarkers for the disease makes accurate diagnosis difficult. Achieving reproducible results using neuropsychological tests and rating scales to measure treatment efficacy requires enormous experience. Because most of the patients are older than 65, co-morbidity and co-medication make recruitment and long term study retention problematic. The need for caregivers to support and supervise patients, and also to help assess drug effects, complicates clinical studies even further. In addition, many studies are being performed in parallel, making patient enrollment extremely competitive.



As a leading science-focused CRO, QPS is especially dedicated to neuroscience research from preclinical through clinical phases. Experience with preclinical development using state-of-the-art disease models has given our experts a profound understanding of the pathogenic mechanisms behind AD and a close familiarity with the pharmacodynamic effects of various treatments. On top of that, QPS has a long tradition of conducting trials involving neurodegenerative diseases such as AD. Our clinicians are aware of the latest diagnostic criteria and the most recent developments in study design to meet the requirements of modern AD research. They also recognize the problems and limitations of currently available cognitive tests and are active in developing and validating new methodologies, in close collaboration with leading world experts.

QPS staff are experienced with a range of imaging techniques and can help coordinate multiple sites to meet uniform quality standards. We monitor the quality of imaging procedures throughout studies. At the same time, we are capable of centralized longitudinal evaluation using sophisticated imaging evaluation software.

As part of an international team standardizing the analysis of CSF biomarkers, QPS can also point to experience in this increasingly important field.

Furthermore, QPS has excellent connections with leading AD researchers, and can therefore support site selection that guarantees the highest quality investigators. Our experience in regulatory affairs helps get trials started according to the shortest timelines. Our clinical team manages and monitors all ongoing studies closely to ensure optimal patient safety as well as reliable data quality.

QPS' experience can reduce your time-to-market and minimize your costs. We will carefully accompany your clinical study from start to finish, putting the right team and protocol in place to make certain your trial runs smoothly. One-on-one communication and flexibility towards the changeable demands of clinical research further smooth the way for your success.

SPEEDY PATIENT RECRUITMENT

Complex protocols, extra demands on caregivers, and competition among the many ongoing studies in this indication make the timely recruitment of an appropriate patient population one of the major challenges of conducting clinical trials for AD. Delays in subject recruitment can adversely affect trial results and escalate costs.

QPS ensures speedy patient recruitment through powerful associations with efficient study sites across Europe, innovative patient recruitment strategies, and close links with academia, SMOs, and specialist networks. We maintain a large worldwide database of investigators to ensure high enrollment rates of patients selected according to strict eligibility criteria.

A specialized QPS team works 24/7 to offer solutions that increase patient enrollment rates.

EFFICIENT PATIENT RETENTION

The enormous amount of time and effort that goes into recruitment of patients for clinical trials in AD makes retention of those subjects throughout the entire trial period imperative. Prevention studies in AD need to be large, may last for several years, and are often associated with high dropout rates.

QPS understands that communicating the benefits of study participation to families affected by AD plays a crucial role in retaining patients through these long trials. A well trained, highly motivated staff of native speakers works with AD patients and their caregivers to support and guide them through the variety of tests and procedures conducted at each visit. The large, specialized hospitals, up-to-date equipment and co-operative staff members at our study sites in Central and Eastern Europe ensure that patient and caregiver participation in each trial is an enriching experience. QPS conducts clinical trials all over Europe and Israel, with an emphasis on countries in Central and Eastern Europe where large numbers of naive patients are ready to give informed consent and are less likely to drop out.

EXPERIENCED INVESTIGATORS

QPS works closely with our principal investigators to ensure that your studies are recruited on time and with qualified subjects. The strong relationships we forge with the investigators who conduct your clinical trials promote the performance of quality studies. We take pride in the fact that the skills of the most experienced investigators are applied to every clinical trial QPS conducts.

PROFICIENT REGULATORY AFFAIRS

Our regulatory affairs team can help you find the most direct route to regulatory submission and approval for your pharmaceutical or biotech product or medical device so you can reach your market faster. We support study design, protocol development, CRF design and all other tasks that arise during planning, conducting, and evaluating clinical studies according to ICH GCP guidelines, in close collaboration with the experts on your own team.

QPS FOR YOUR NEXT ALZHEIMER'S DISEASE TRIAL

Whether you are planning a clinical trial of small molecules, biologics, immunotherapies or medical devices, QPS has the experience and resources to handle your study and deliver high quality data in time. Choose QPS for your next AD trial!

Should you want to discuss your questions in more detail with one of our experts, please contact us directly at: info@qps.com

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2 Knebl JA, Patki D. Recruitment of Subjects Into Clinical Trials for Alzheimer Disease. JAOA. September 2010;110(9):S43-S49.

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