

ALZHEIMER'S DISEASE: PROBLEM SOLVING FOR UNINTERRUPTED TRIAL PROGRESS

DESCRIPTION

Worldwide Clinical Trials was retained to intervene in a Phase IIb, multinational, randomized, double-blind, placebo-controlled study in subjects with progressive cognitive decline compatible with the diagnosis of prodromal Alzheimer's disease (AD).

CHALLENGE

- The original CRO had failed to meet enrollment expectations due to inadequate vetting of site capabilities for this unique diagnostic category, which required the use of multiple sophisticated screening assessments that served as a "gatekeepers" for patient eligibility.
- The study had been launched in over 30 centers by the sponsor with virtually no patient enrollment prior to Worldwide Clinical Trials' engagement.

SOLUTION



Dedicated a Worldwide neuropsychologist to oversee clinical monitoring, site selection and enrollment

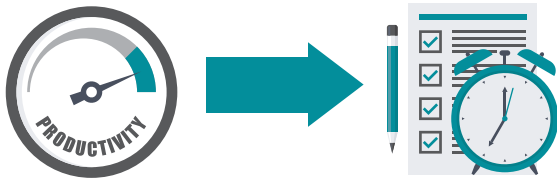


Structured the sequence of test applications for compatibility with protocol design and standard of care



Reevaluated site attributes and rater qualifications for administration of a battery of neuropsychological tests, many of which required specialized training in a highly codified sequence

OUTCOMES



Accelerated patient randomization led to study completion one week prior to original target date.

As acknowledgment of Worldwide's material contribution to concepts, analysis and implementation of the study, Worldwide's scientific staff are co-authors in the subsequent *Journal of Alzheimer's Disease* article.

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