WORLDWIDE CLINICAL TRIALS

CASE STUDY

INNOVATIVE "VIRTUAL WAITING ROOM" APPROACH REDUCED EARLY PHASE STUDY TIMELINES BY 6 MONTHS

DESCRIPTION

Two separate Phase I, double blind, placebo-controlled studies investigated the safety, tolerability, and pharmacokinetics of a blinded study drug, using single and multiple ascending dose(s) (SAD-MAD), in patients with Alzheimer's disease (AD).

More than 20
U.S. and European sites simultaneously enrolled approximately
140 patients
into cohorts.

CHALLENGE

One primary challenge encountered in both studies was related to the method of cohort management and escalation requirements. Complex protocol designs allowed patients in one of the studies to roll over from the SAD to MAD cohorts; and in the second study, patients who discontinued early could be replaced, making accurate tracking critical.

The researchers needed to manage rapidly changing recruitment efforts and notify sites of fluctuating accrual speed and limits in real time. The trials involved moving some patients from screening to randomization, holding others back, and opening/closing recruitment across multiple sites simultaneously.

At risk were the threat of over-enrollment; the possibility that potentially eligible patients could be overlooked due solely to the timing of cohorts or procedural delays; and recruitment fatigue, as sites were called upon to repeatedly commence and halt their recruitment efforts.

SOLUTION

A "virtual waiting room" was created using interactive response technology (IRT). This enabled investigators to recruit patients on an ongoing, rolling basis with a "next-in-line" approach. The IRT-assisted cohort optimization strategy facilitated the uninterrupted recruitment of patients with centralized control across multiple sites, resulting in:

- Faster activation and closure of cohorts conducted via IRT based on safety review meetings,
- Expedited dosing approvals by the medical monitoring staff,
- A seamless rollover of patients from single- to multiple-dose cohorts (SAD-MAD), and
- Less disruption in study momentum and reduced recruitment fatigue

OUTCOMES

This strategy saved an average of 2.9 weeks per cohort. In a 10 cohort SAD-MAD study, it reduced overall timelines by over six months compared to a standard recruitment approach.

Routine contact with sites coupled with a rolling data review resulted in the successful achievement of having over 90% of data clean at all times. This permitted timely scheduling of the intra-cohort safety review meetings.