SPEAKout

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Innovations in Alzheimer's Clinical Trial Operations Promise to Smooth Transitions

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The global impact of Alzheimer's disease continues to increase. By 2050, the Alzheimer's Association expects the number of people diagnosed with dementia to increase to 131.5 million, and currently, Alzheimer's is a direct cause of dementia in an estimated 60%-80% of the 46.8 million people living with degenerative brain disease[1,2]. Despite more than a decade of frustration in finding effective disease-modifying therapies, there are new opportunities to reduce the time and risk of AD drug development through improvements in trial operations[3].

For example, there has been an effort led by the innovative Alzheimer's disease researchers of Worldwide Clinical Trials and others to ensure a seamless transition from single to multiple dose cohorts of patients (SAD-MAD) within a single study often consisting of up to 10–12 cohorts across as many sites. Of note, some sites may be engaged early on in the enrollment process while others are activated in a staggered approach.

Unlike studies seeking to enroll healthy volunteers at a single site, the majority of early-phase cohort studies in patient populations are conducted across multiple sites, with the number of sites being dependent upon sample size, length and complexity of the study, and the recruitment potential of the indication of interest.

"Virtual waiting room" enables proactive management of early-phase Alzheimer's study tasks

In an effort to increase the predictability of timelines, stabilize enrollment fluctuations, master the timing and unpredictability of complex cohort designs, fight recruitment fatigue, and ensure that all eligible patients who can be randomized actually are randomized, Worldwide's researchers created a technology-assisted "virtual patient waiting room" in partnership with the study sponsor [4].

This virtual waiting room permits investigators in Alzheimer's disease research to recruit patients on an ongoing, rolling basis with a "next-in-line" approach that permits multiple sites to simultaneously enroll patients into a single cohort, while continuing to recruit for the upcoming cohorts. Recruited patients who meet eligibility criteria when randomization is closed for a specific cohort are simply placed in the virtual patient waiting room while screening activities continue for the subsequent cohorts. This simple maneuver stabilizes recruitment efforts and patterns so that sites do not have to be shut down and restarted multiple times.

Technology ensures all eligible patients are enrolled and there is no over-enrollment

By utilizing this strategy, the appropriate enrollment of each individual cohort can be more easily managed simply by proper programming of the interactive response technology (IRT) to ensure that all eligible patients are randomized, that there is no over-enrollment within the cohort and that the time between cohorts is minimized. Importantly, forecasting important metrics such as the last patient visit in each cohort can be easily achieved.

Conclusion

In summary, the technology-assisted cohort optimization strategy outlined above results in faster progression through cohorts in Alzheimer's disease research while preserving study data integrity in early-phase multi-center studies, which saves both time and money.

To learn more about Worldwide's early phase clinical research services, please contact Worldwide Clinical Trials at +1 (610) 964-2000 or visit www.worldwide.com.

References

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