National Alzheimer's Project Act (NAPA)

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The Capacity of Alzheimer's Disease Clinical Trial Sites Unlikely to Meet the Demands of Pending Therapeutic Clinical Trials

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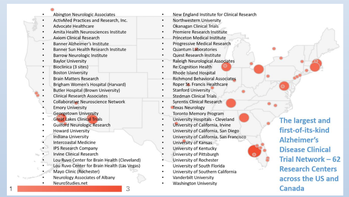
Introduction

While attention is often given to the Alzheimer's disease (AD) pipeline and successful recruitment, the capacity of current AD trial centers to enroll and execute these trials is equally important. Even if we can recruit qualified participants, sites that can accommodate these participants are limited. The Global Alzheimer's Platform (GAP) Foundation estimates that the number of qualified sites in North America to conduct pending AD clinical trials represents less than 50% of the number of sites required to meet the demand of AD clinical trials in the pipeline. This shortage puts the timely discovery of a cure for AD at risk.

Focusing on the capacity challenge in AD trials will reduce the time and cost of AD clinical trials, and– more importantly – will increase the likelihood that all the trials currently anticipated are completed on a timely basis thereby speeding the delivery of innovative medicines to those suffering from or at risk of AD.

GAP Site Network



Methods

Researchers Against Alzheimer's (RA2) publishes an annual AD development pipeline. According to the 2017 RA2 report, 55 phase 2 or 3 complex therapeutic trials for treatment or prevention of AD/Mild Cognitive Impairment (MCI) will be enrolling in 2018-2019*.[1] Approximately 25,277 participants will need to be randomized for these clinical trials in North America in the next 24 months.

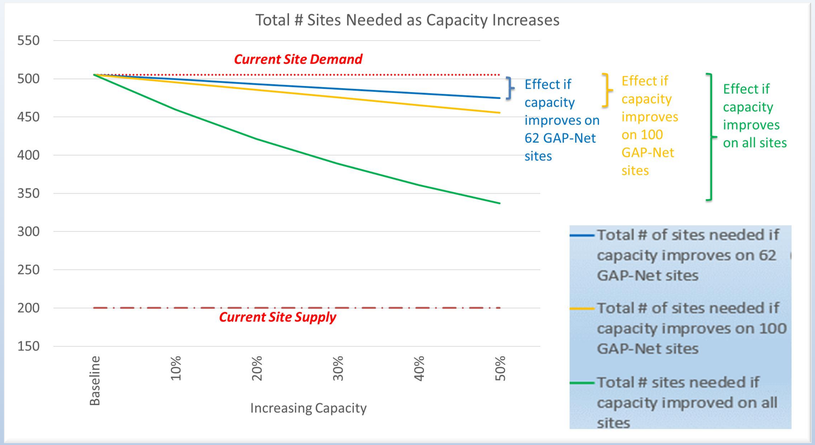
Global Alzheimer's Platform Network (GAP-Net) metrics were used to calculate the current capacity of the field to meet this level of enrollment. GAP-Net consists of 62 AD trial centers, both private and institutional, dispersed across North America. GAP collects metrics from its sites on recruitment and site performance. Data gleaned from GAP-Net were used to extrapolate the predicted performance of the whole field.

In 2017, GAP-Net sites randomized an average of 25 participants per site into comparable phase 2 and 3 therapeutic trials. Extrapolating this average to all sites over 2 years, GAP estimates that a total of 505 sites (including GAP-Net sites) would be needed to randomize 25,277 participants in AD clinical trials.

There is no absolute agreement on how many sites in North America are equipped to conduct the trials described in the RA2 report. GAP, and other observers of the field, conservatively estimate that there are approximately 200 qualified AD trial sites in North America. Therefore, site demand exceeds capacity by 250%. These projections pose important questions about how the field will address the need to complete clinical trials in a timely fashion.

Results

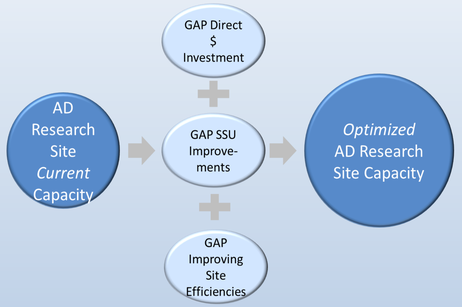
If current GAP-Net site capacity could be increased by 50% (+12.5 participants per year) through GAP's optimization efforts and capital investment, 30 fewer sites would be needed. Based on GAP-Net's projected growth in 2018 to a total of 100 GAP-Net sites, if the number of participants could be increased by 50%, 50 fewer sites would be needed. Even a modest increase of 10% improvement in enrollment across 100 sites would result in 10 fewer sites being needed overall.



Discussion

GAP is analyzing a number of tactics in the face of this strategic threat. GAP's strategy for addressing the problem of limited site capacity is to enable sites to perform more efficiently and thus better employ their current resources as well as to invest more resources into sites.

- By building an organized consortium of sites – all focused on operational improvement and enrollment innovation – GAP is increasing site capacity or, in some cases, creating new capacity to enroll participants. Similar models exist in other therapeutic areas such as cancer and stroke.
- In addition, GAP is investing and stimulating investment to improve infrastructures. In previous research, GAP has been able to show that investing in site infrastructure can substantially increase enrollment.[2]
- GAP facilitates and supports GAP-Net site start-up (SSU) activities including a central IRB, common contract template, and a high-touch concierge start-up model.
- GAP has developed its Site Process Optimization program to improve the efficiency and effectiveness of the study pre-screening and screening processes through formal process evaluations.



Conclusion

To successfully execute trials in the AD pipeline, changes to the current system are critical. GAP's projections suggest that many pending trials cannot be completed on schedule without addressing the shortage of clinical trial capacity. It's likely that these changes will come from a broad spectrum of solutions. GAP-Net is poised to increase site capacity both by increasing the total number of sites, shortening the duration of AD clinical trials, collaborating in infrastructure investment, and facilitating site optimization activities.

In addition, GAP is incubating novel pre-screening technologies which are intended to reduce the rate of screen failures, thereby creating additional site capacity. While GAP believes these tactics will make a significant contribution to reducing the shortage, larger and more systemic strategic programs need to be considered to close the gap between pending AD clinical trial demand and the supply of clinical trial sites in North America.

References

[1] Alzheimer's Drugs in Development Pipeline. UsAgainstAlzheimers Web site. https://www.usagainstalzheimers.org/sites/default/files/alzheimers-drugs-development-pipeline-2017.pdf?utm_source=RA2Pipeline&utm_medium=PressRelease. Released July 2017. Accessed June 7, 2018.

[2] Richard Mohs, Gabe Goldfeder, et al. Novel Recruitment Strategies for Clinical Trials. Oral presentation at 2017 Alzheimer's Association International Conference; July 2017; London, England.

* The RA2 report that was recently released in July 2018 did not materially impact our results.

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