Case study

Estimating the benefits of digital and plasma-based pre-screening in Alzheimer's Disease trial recruitment

About F. Hoffmann-La Roche Ltd.

Roche, founded in 1896, is one of the world's largest biotechnology companies and a global leader in in-vitro diagnostics. With over two decades of Alzheimer's research, Roche is advancing early detection and treatment through investigational medicines, digital tools, and diagnostics. Roche is recognized for its commitment to sustainability and expanding healthcare access worldwide.

The opportunity

- Pre-screening using blood tests and/or digital cognitive assessments (DCAs) offers a significant opportunity to enhance Alzheimer's Disease (AD) clinical trials by reducing patient burden, improving screening efficiency, and lowering recruitment costs.
- DCAs can streamline participant selection by allowing low-cost, scalable, and remote assessments. This approach accelerates trial timelines, increases outreach and diversity, and facilitates the evaluation of new treatments, addressing critical challenges in AD research and clinical development.

The challenge

- AD clinical trials face very high screen failure rates, with up to 95% of candidates not meeting eligibility criteria, leading to increased recruitment costs, trial delays, and patient burden.
- Current pre-screening methods with in-clinic neuropsychological assessments are often inefficient and time-consuming, creating bottlenecks.
- Additionally, challenges persist in collecting efficient and scalable data from diverse and inclusive populations, further complicating efforts to advance AD research and treatment development.

The approach

- Using a bottom-up approach, starting from a target number of participants to be recruited, we developed a staged recruitment model using assumed conversion rates and per-participant costs, benchmarked against literature and global studies (e.g., Gantenerumab).
- By creating twelve forecast models, we combined two AD populations (pre-symptomatic, prodromal), two recruitment channels (general practitioner clinics,

memory clinics), and three pre-screening methods (DCA, blood-based biomarkers (BBBM), and DCA followed by BBBM.

- Prevalence rates and performance data were used from existing literature, recent AD studies, and aggregated vendor information to estimate industry averages for screening efficacy.
- Relative costs for each screening step were obtained from vendors and aligned with benchmarks from global studies like Gantenerumab.
- DCA screens for cognitive function, while BBBM enhances amyloid positivity detection, guiding efficient participant recruitment.

The impact

- ✔ Pre-screening, especially combining DCA followed by BBBM, reduces recruitment costs by up to 35% and decreases on-site screening by up to 60%, optimizing resource use.
- ✔ Minimizing screen failures, particularly for costly PET scans, accelerates trial timelines. This results in faster time to patient, lower overall costs, and reduced patient burden.
- ✔ Remote DCA pre-screening improves access to diverse populations, supporting inclusive recruitment and aligning with regulatory priorities.
- ✔ BBBM is more effective for preclinical studies, while DCA excels in prodromal-stage trials. Combining both methods offers the highest cost savings (13-35%).
- ✔ Across all scenarios, pre-screening either lowered recruitment costs or was cost-neutral. It reduced the need for on-site screening by up to 60%, streamlining recruitment and enhancing trial success.

> "Combining digital biomarkers for detecting cognitive symptoms with blood biomarkers for detecting underlying neuropathology is a promising approach for cost-effective and minimally invasive clinical trial recruitment in AD and beyond."

— Dr. Tobias Bittner
Distinguished Scientist & Biomarker Leader, Genentech/Roche

This case study was adapted from the poster "**Estimating the benefits of pre-screening Alzheimer's trials using blood-based biomarkers and digital cognitive assessments**" by N. Linz, R. Ullmann, J. Tröger, A. König, R. Croney, T. Bittner, and T. Perumal. The poster was presented at the 2024 Clinical Trials on Alzheimer's Disease (CTAD) conference. While the poster is not available online, the abstract can be found here.