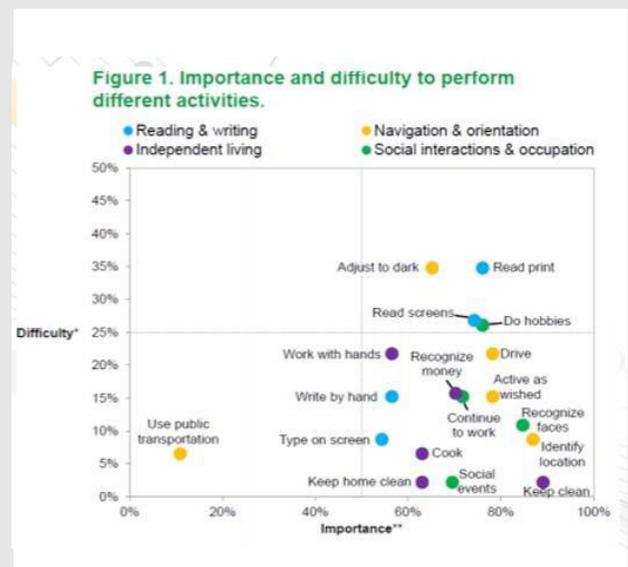


## ANALYTICS DRIVEN RESEARCH TO IMPROVE PATIENT QUALITY OF LIFE

A tier 1 pharmaceutical company that has a globally marketed product for age-related macular degeneration (AMD) and diabetic macular edema (DME) was planning to launch a complement to its current product with a better pharmacokinetic/pharmacodynamic (PK/PD) profile and lower frequency of injections. However, AMD patients are entering clinical trials with increasingly better visual acuity, and it becomes difficult to measure additional benefits of new drugs under existing endpoints.

Certara conducted stakeholder research to define a new clinical trial endpoint in wet AMD and DME that would offer a better measure of patient visual function than the current standard of visual acuity. The approach taken included:

- An analytics-driven and stakeholder research approach where the US, UK, French, and Canadian teams conducted multinational, individual, structured patient, regulator, KOL, physician and payer interviews.
- Patient interview questionnaire was developed for investigators, leveraging available literature and external expert advice (i.e. patient representatives and KOLs)
- 18 daily activities were identified and assessed according to importance and difficulty to perform among AMD or DME patients



“ In a mature and competitive market, Certara helped our client define endpoints in multiple markets that would drive differentiated value at the regulator, payer, prescriber, and patient levels, accelerating development by integrating commercially vetted trial designs into clinical development plans. ”

By establishing and validating a new endpoint, Certara provided this client with a fundamentally stronger value proposition for its product, supporting rationale for pursuing a new direction in their upcoming trials. Our engagement demonstrated Certara's ability to leverage traditional market research into value-driven insights that are patient-centered. In a situation when the stakes for return on investment are very high and the potential market opportunity is significant, the Tier 1 pharma needed more than a vendor providing data points. They engaged us for reliable advice from a strategic consulting partner.



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