

# GlauCAT™ in Clinical Trials

Including CATs as a study endpoint in a glaucoma clinical trial for a novel treatment intervention: how PROMinsight is supporting pharma companies to adhere to regulatory body requirements.

## Summary

The glaucoma quality of life CAT "GlauCAT™" <sup>1,2</sup> is currently being used as a secondary endpoint to measure 12 domains of glaucoma-specific quality of life in a large clinical trial for patients with glaucoma at the Singapore National Eye Centre.

The goal of the trial is to determine the clinical and patient-centered effectiveness, and cost-effectiveness of minimally invasive glaucoma surgery (MIGS) in patients with glaucoma.

## GlauCAT in action



Patients answered all 12 GlauCAT™ QoL tests on site as part of their clinical testing protocol. Tests included:



Activity limitation



Mobility



Emotional well-being



Concerns



Treatment inconvenience



Ocular comfort



Visual symptoms



Social



General inconvenience



Driving



Lighting



Economic



Patients completed the GlauCAT™ tests on an internet-enabled tablet via a password-protected web portal.



GlauCAT™ quality of life data were automatically saved and stored on the PROMinsight database, ready for instant download and data analysis.

## Results

To date, over 50 patients have successfully answered the 12 GlauCAT™ tests as part of their clinical testing protocol with very little patient or researcher burden.

Recently released data from the study team has revealed large improvements in seven GlauCAT™ domains at 6 months post-surgery compared to pre-surgery values in 24 patients with follow-up data available.

For example, patients reported a 15 point (out of 100) improvement in Visual Symptoms; a 9.5 point improvement in Concerns; an 8.5 point increase in Emotional well-being; and a 7 point improvement in Ocular Comfort Symptoms.

<u>GlauCAT™</u> domains	Increase in score (mean)	Effect size
Visual Symptoms	14.7	0.82
Ocular Comfort Symptoms	6.6	0.52
Concerns	9.5	0.60
Emotional	8.5	0.43
Lighting	6.4	0.41
General Convenience	6.1	0.34

These findings are amongst the first in the world to show that PHACO-MIGS can significantly improve a range of quality of life outcomes in patients with early stage glaucoma and cataract and demonstrate the importance of using valid, precise and comprehensive glaucoma-specific instruments such as GlauCAT™.

With CATs that are fast, precise and easy to use, the PROMinsight system supports pharma companies in adhering to requirements of regulatory bodies like the Food and Drug Administration to include PROMs as study endpoints.

## Key Figures



>50 patients



Median **2 mins 20 secs** to take each CAT test, **27 mins 30 secs** for all 12 tests



**12** individual quality of life outcomes measured



**100s** of hours saved in data entry and psychometric analyses

## Research Team Experience

"The use of GlauCAT™ in patients has been incredibly easy. The clinical flow remains unchanged and patients can complete the questionnaire with just a few clicks whilst waiting in turn to see their doctor. I have heard from patients that it is "no problem at all", "easy to understand and simple to reply" "over before I knew it" GlauCAT™ will therefore be a strength to any clinical trial in glaucoma and I am delighted to support it!"

*Principle Investigator and Ophthalmologist – Singapore National Eye Centre*

"GlauCAT™ was easy to use and efficient, and patients found the questions were straightforward and easy to understand."

*Senior Clinical Research Coordinator – Singapore National Eye Centre*

## Insights & Future Plans

### Insights

- Built in data analytics to produce real time data and simple charts with just a few clicks would be invaluable for ongoing clinical trials, especially during interim reporting, and will provide reassurance to sponsor and industry partners
- GlauCAT™ could be used to support post-trial regulatory, fundraising and marketing activities
- For some trials, it could save time if patients can answer GlauCAT™ at home rather than during their clinic visits
- From a user perspective, it would be good to display how many remaining domains are left to administer to gauge and monitor progress during test taking



### Next Phase

- The PROMinsight software team will explore the possibility of enhancing the data analytic capability of our products
- The PROMinsight marketing team will explore the potential of GlauCAT™ to support pharma companies with post-trial activities
- Future trials will explore the feasibility of sending patients a secure link to the PROMinsight platform and relevant GlauCAT™ tests 1 day prior to their clinical trial visit
- The PROMinsight software team will explore adding this feature to our testing platform



## Summary

The findings and insights from this glaucoma study have demonstrated the value of implementing CAT technology for PROM assessment in clinical trials, highlighting the importance of the PROMinsight platform and associated CAT testing suite in facilitating the inclusion of PROMs as study endpoints and satisfying regulatory body requirements.

## References

1. Khadka J, Fenwick E, Lamoureux E, Pesudovs K. (2015). Item banking enables stand-alone measurement of driving ability from an activity limitations item set Optom Vis Sci, Accepted.
2. Khadka J, McAlinden C, Craig JE, Fenwick EK, Lamoureux EL, Pesudovs K. (2015). Identifying content for the glaucoma-specific item bank to measure quality-of-life parameters. J Glaucoma, 24(1): 12-19.

We are here to help answer any question you might have. Our international team would be happy to discuss your testing needs.



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