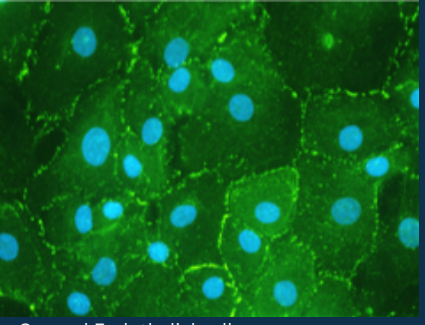

Corneal Endothelial cells.
Image: Cell and Tissue Therapies WA.

REVOLUTIONISING CORNEAL TRANSPLANTATION: ADVANCING CLINICAL-GRADE CELL INJECTION THERAPY

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CELL AND GENE THERAPIES

Corneal endothelial cell failure is a leading cause of blindness worldwide, yet donor corneas for transplantation remain in critically short supply. **Dr. Evan Wong**, Ophthalmologist at the Lions Eye Institute, is developing a corneal cell injection therapy, offering a minimally-invasive approach to treating corneal blindness.

TIA has supported this project by awarding both a Technical Feasibility Assessment (TFA) and a Pipeline Accelerator award. The TFA provided expert guidance from Cell and Tissue Therapies WA (CTTWA) at the Royal Perth Hospital on product development requirements for Dr Wong's clinical-grade, good manufacturing practice (GMP)-compliant cultured corneal endothelial cell (CEC) therapy. The TFA enabled progression to a Pipeline Accelerator voucher, enabling CTTWA to establish a GMP-compliant culture protocol and expand corneal endothelial cells from donor tissue. The team has developed a manufacturing protocol for enough cells for approximately 130 therapeutic doses from a single donor.

This technical transfer to a GMP facility is a crucial step in clinical translation and the team is now looking to proceed to Australia's first clinical trial of cultured CEC injection therapy, positioning Australia as a pioneer amongst global leaders in the field.

Unlike traditional corneal transplants, which require a 1:1 donor-to-recipient ratio and complex surgical procedures, CEC injection therapy offers a scalable, minimally invasive alternative. It has the potential to improve access to treatment in rural hospitals, enhance donor-to-recipient efficiency, and drive future commercialization and export through advanced manufacturing and logistics.

This initiative represents a unique collaboration between Singapore Eye Research Institute, Lions Eye Institute and Eye Bank, and CTTWA, bringing together expertise in corneal donor material, transplantation, and clinical-grade cell therapy manufacture. As the team prepares for a Phase I clinical trial, efforts will focus on refining cell preservation techniques and addressing logistical challenges for broader distribution. This ground-breaking work could revolutionise the treatment of corneal endothelial failure, improving patient outcomes in Australia and beyond.

> "The results with CTTWA have shown that we can generate well over 100 treatments from a single donor – this is a game-changer. The support from TIA to get this off the ground was invaluable" **Dr Evan Wong**

Impact:

TRL 1 TRL 2 TRL 3 **TRL 4** **TRL 5** **TRL 6** TRL 7 TRL 8 TRL 9