Bacteriophage. Image: Rebecca Bamert, Lithgow Laboratory, Monash University.

A NEW FRONTIER IN FIGHTING SUPERBUGS: BACTERIOPHAGE THERAPY IN AUSTRALIA

Published on 28th August 2025

CELL AND GENE THERAPIES

A/Prof Anthony Kicic and his team at The Kids Research Institute Australia are advancing bacteriophage therapy, a new way of fighting antimicrobial resistance. In 2022, a Technical Feasibility Assessment (TFA) voucher enabled the team to engage with **A/Prof Zlatibor Velickovic**, Facility Director at the Cell and Tissue Therapies Western Australia (CTTWA), to explore manufacturing pathways and regulatory considerations, laying the groundwork for future development.

Whilst the global regulatory framework for Therapeutic Goods Administration is evolving, the TFA voucher provided an opportunity to assess manufacturing scenarios and identify pathways for eventual patient treatment. The collaboration clarified the strict requirements of Good Manufacturing Practices (GMP), highlighting the challenges of transitioning from research to a regulated therapeutic.

This initial engagement has grown into a three-year partnership with CTTWA. The research team established two PC2 laboratories within the Centre for Advanced Therapies, equipped to meet GMP compliance. So far, they have successfully completed three batches of phage manufacturing, with more in progress.

The project has secured $650,000 from the Western Australian Future Health and Research Innovation Fund and a $1,800,000 donation from the Stan Perron Charitable Foundation. This will support a 3,000 bacteriophage library against many species of bacteria that develop antibiotic resistance, preclinical safety assessments, and manufacturing validation in preparation for clinical delivery. A further $1,900,000 has been awarded by the MRFF to support a clinical trial to treat *Pseudomonas aeruginosa* lung infections.

Most significantly, the project has translated into real-world clinical impact. Through Australia's Special Access Scheme, two patients in Western Australia - one adult and one child - have received phage therapy, successfully clearing their infections without adverse effects. This is a significant milestone in demonstrating the safety and therapeutic potential of bacteriophage treatments.

> "The TIA voucher enabled engagement with parties experienced in the manufacture of biologics, that then identified how phages could be produced and supplied in Australia" **A/Prof Kicic**

Impact:

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