



Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

NOTIFICATION OF APPLICATION

Receipt of licence application from Novotech (Australia) Pty Ltd for a clinical trial of genetically modified *Lactobacillus brevis*

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 197) from Novotech (Australia) Pty Ltd to conduct a clinical trial of genetically modified (GM) *Lactobacillus brevis* for treatment of inflammatory bowel disease. A summary of the application is posted on our [website](#) (search for DIR 197).

The proposed clinical trial would take place over a period of 7 years and enrol up to 60 trial participants. The purpose of the trial is to evaluate safety of the GM treatment in healthy adults and the safety and efficacy of the treatment in adults with ulcerative colitis.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. This is expected to be released for public comment and advice from experts, agencies and authorities in **early July 2023**. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the full application or the summary, please contact the OGTR and quote the reference number DIR 197.

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