



Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of a genetically modified adenovirus for treatment of rectal cancer (DIR 222)

The Gene Technology Regulator is assessing an application from Novotech (Australia) Pty Limited to conduct a clinical trial, under limited and controlled conditions, of a genetically modified adenovirus for treatment of locally advanced rectal cancer. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 40 trial participants would be treated over a 4 year period.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via the [consultation hub](#), or from the contacts below. Submissions should reference DIR 222 and be received by **5 March 2026**.

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