



Australian Government

Department of Health

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial with a genetically modified *Vaccinia virus* based treatment for solid cancerous tumours

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 *Vaccinia virus* based treatment for solid cancerous tumours. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 150 trial participants would be treated over a 5 year period.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions on issues relating to the protection of human health and safety and the environment prior to making a decision on whether or not to issue the licence. The consultation RARMP and related information can be obtained via the contacts below. Submissions should reference DIR 179 and be received by **24 February 2021**.

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