



Australian Government

Department of Health

Office of the Gene Technology Regulator

18 November 2020

Invitation to comment on a clinical trial of genetically modified human adenovirus cancer treatment

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 human adenovirus for bladder cancer treatment. The proposed trial would be conducted at 5 hospitals which would be located in NSW and VIC. Up to 60 trial participants would be treated over a 5 years 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 177 and be received by **22 December 2020**.

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