



**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 Vaccinia virus as a treatment for solid tumours***

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 208) from Novotech (Australia) Pty Ltd to conduct a clinical trial with genetically modified (GM) Vaccinia virus with selectivity for tumours. A summary of the application is posted on our [website](#) (search for [DIR 208](#)).

The clinical trial is proposed to take place at hospitals and clinical trial sites within Australia over a period of 5 years. Up to 40 patients in Australia would receive single doses of the GM *Vaccinia virus* to evaluate the treatment's safety and efficacy.

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 **mid-December 2024**. 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 application or the summary, please contact the OGTR and quote the reference number DIR 208.

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