Questions & Answers on licence application DIR 222 – Clinical trial of a genetically modified adenovirus for treatment of locally advanced rectal cancer

What is this application for?

Novotech (Australia) Pty Limited is seeking approval for a clinical trial of a genetically modified (GM) adenovirus for treatment of locally advanced rectal cancer. In most patients with advanced cancers, chemotherapy, radiotherapy or surgical removal does not fully eliminate tumours. Thus, there is a need for novel treatments.

The proposed treatment uses a GM adenovirus, which has been designed to preferentially multiply in, and kill cancer cells. It is predicted to provide therapeutic benefit to cancer patients undergoing chemoradiotherapy for advanced rectal cancer. The GM adenovirus would be manufactured overseas and imported into Australia. It would be administered to up to 40 patients with locally advanced rectal cancer at clinical trial sites and hospitals in Australia.

What other regulatory processes apply to this trial?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration (TGA), which address the safety of trial participants. Before commencing, the trials would require ethics approval, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM human adenovirus treatment will also require approval from the Department of Agriculture, Fisheries and Forestry.

How has the GM adenovirus been modified?

The GM treatment is based on a non-GM adenovirus which lacks several genes, making it infect and multiply in cancer cells and not in healthy cells. It has been used in clinical trials to treat different cancers in people. The GM treatment has been modified from this virus by insertion of two genes encoding for one protein that stimulates the body's immune system to recognise and kill tumour cells.

What is the purpose of the trial?

The trial is to assess the safety, tolerability and efficacy of the GM adenovirus for treating locally advanced rectal cancer.

Has the GM treatment been previously tested or used?

The GM treatment has been used in Phase 1 clinical trials in the United Kingdom and United States.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, several licence conditions have been drafted to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM treatment. For example, there are conditions relating to preparation and administration of the GM treatment, secure transport and storage of the GM treatment and appropriate waste disposal. Full details of the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 222 are available on the OGTR website (search DIR 222), the consultation hub or via the contacts listed below. You are invited to submit your written comments (via the consultation hub or by email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed clinical trial. Please note that issues such as **patient safety, quality and efficacy of a therapeutic products, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **5 March 2026**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR website

Tel: 1800 181 030 E-mail: ogtr@health.gov.au