



**Australian Government**

**Department of Health, Disability and Ageing**

**Office of the Gene Technology Regulator**

11 June 2025

**Notification of decision on application DIR 213 from Novotech (Australia) Pty Ltd for the clinical trial of a genetically modified human adenovirus for treatment of melanoma**

The Regulator has issued a licence DIR 213 to Novotech (Australia) Pty Ltd, authorising the clinical trial of a genetically modified (GM) human adenovirus for the treatment of melanoma.

The trial is proposed to take place at clinical trial sites and hospitals in Australia.

The Risk Assessment and Risk Management Plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

Submissions are summarised in Appendix A and Appendix B of the RARMP, together with information about how the issues raised relating to risks to human health and safety or the environment were considered in finalising the RARMP.

The finalised RARMP concludes that this clinical trial poses negligible risks to the health and safety of people and the environment, thus it does not require specific risk treatment measures. However, licence conditions have been imposed to limit the number of trial participants, limit the location of the clinical trial to hospitals and clinical trial sites, limit the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread in the environment, as these were important considerations for the RARMP.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the [DIR-213](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

**Office of the Gene Technology Regulator**

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