Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of an IV administered GM vaccinia virus (CLD-401) for the treatment of advanced solid tumours (DIR-232)

The Gene Technology Regulator is assessing an application from Avance Clinical Pty Ltd to conduct a clinical trial, under limited and controlled conditions, of a genetically modified virus for treatment of solid tumours. The trial is proposed to take place at clinical trial sites and hospitals in Australia over a 5-year period.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via the consultation hub at https://consultations.health.gov.au/ogtr/dir-232-consultation, or from the contacts below. Submissions should reference DIR-232 and be received by **8 January 2027**.

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