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Office of the Gene Technology Regulator

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Invitation to comment on a clinical trial with a genetically modified human adenovirus COVID-19 vaccine

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 human adenovirus COVID-19 vaccine. The purpose of this clinical trial is to assess an intranasal administration of a GM vaccine for COVID-19, which is different to the intramuscular administration of other COVID-19 vaccines currently in use. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 1000 trial participants would be treated over a 5 year 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 184 and be received by **26 May 2021**.

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