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Invitation to comment on a clinical trial with genetically modified *Bordetella pertussis* for the prevention of whooping cough

The Gene Technology Regulator is assessing an application from Novotech (Australia) Pty Ltd to conduct a clinical trial, under limited and controlled conditions, of a genetically modified *Bordetella pertussis*. The purpose of this clinical trial is to assess a GM vaccine for the prevention of whooping cough. This vaccine would be administered intranasally, which is different to the intramuscular administration of other pertussis vaccines currently in use. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 300 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 185 and be received by **4 November 2021**.

Office of the Gene Technology Regulator
MDP 54 GPO Box 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 Website: www.ogtr.gov.au
E-mail: ogtr@health.gov.au