



17 December 2015

## Invitation to comment on draft assessment for clinical trial of a genetically modified virus for treatment of liver cancer

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 140 from Clinical Network Services Pty Ltd (CNS) to conduct a Phase 3 clinical trial of a genetically modified (GM) virus for the treatment of liver cancer. CNS has proposed that the GM virus be administered to up to 50 adult volunteers with advanced liver cancer, in conjunction with a standard cancer treatment. It would be injected directly into tumours by trained medical staff. Hospitals throughout Australia may be involved in the trial. CNS has requested a period of up to 5 years to allow for any follow-up studies that may be required.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed clinical trial would pose negligible to low risk to human health and safety or to the environment. Licence conditions are proposed to manage the risk and to limit the scale and scope of the clinical trial and restrict the spread and persistence of the GMO.

The Regulator welcomes written submissions on the RARMP to inform the decision on whether or not to issue a licence. The consultation RARMP and related documents can be obtained from the OGTR website under '[What's New](#)' or by contacting the Office. Please quote application DIR 140 in any correspondence.

Submissions should be received by close of business on **27 January 2016**.

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