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# NOTIFICATION OF APPLICATION

**Receipt of licence application (DIR 144) from Clinical Network Services Pty Ltd for a
clinical trial with attenuated genetically modified influenza vaccines**

The Office of the Gene Technology Regulator (OGTR) has received a licence application from Clinical Network Services Pty Ltd (CNS) to conduct clinical trial of genetically modified influenza (flu) vaccines. A summary of the application is posted on our website under ‘[What’s New](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/new-index-1)’.

CNS proposes that qualified health care professionals nasally administer the GM flu vaccines to a total of up to 500 healthy adult male volunteers, over a period of up to 5 years. The vaccines would be administered at clinical facilities. One clinical site in Queensland has been confirmed for the trial but other sites may be engaged. The applicant has proposed a number of control measures to restrict the spread and persistence of the GM vaccine strains and their genetic material.

Clinical trials must also be conducted in accordance with requirements of the *Therapeutic Goods Act 1989*, which is administered by the Therapeutic Goods Administration (TGA). Clinical trials must have approval from the Human Research Ethics Committee at each trial site, and must be conducted in accordance with the National Statement on the Ethical Conduct in Research Involving Humans. Import of the GMO would require a permit from the Department of Agriculture.

OGTR is preparing a Risk Assessment and Risk Management Plan for the application. This is expected to be released for comment from the public, experts, agencies and authorities in May **2016**. At least 30 days will be allowed for the submission of comments.

If you have any questions or would like to receive a copy of the full application or the summary (quoting the reference number DIR 144), please contact the OGTR.

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