

Questions & Answers on licence DIR 144

Clinical trial of genetically modified (GM) influenza vaccines

What does this licence allow?

Clinical Network Services Pty Ltd (CNS) has received an approval under *the Gene Technology Act 2000* to conduct clinical trials of GM influenza vaccines. The trials would involve administration of the GM flu vaccines to up to 500 healthy adult male volunteers over a period of 5 years.

What other regulatory approvals apply to this trial?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration (TGA), which address the safety of trial participants, and the National Statement on the Ethical Conduct in Research Involving Humans. The trial will require approval from, and oversight by, the Human Research Ethics Committee at each clinical site. As the GM vaccines will be imported, an import permit must be obtained from the Department of Agriculture and Water Resources.

What is the purpose of the proposed clinical trial?

The primary purpose of the clinical trials is to assess the safety and tolerability of a new type of influenza vaccine, known as SAVE flu vaccines, compared to another type of GM influenza vaccine, FluMist.

How are the GM vaccines modified?

For the GM SAVE flu vaccine strains, a large number of point mutations will be introduced into two genes, which determine the major flu antigens, of selected flu strains. The mutations don't change the proteins which the virus makes during infection but reduce the efficiency with which they are made. This is also expected to reduce their ability to grow and cause disease, making them useful as vaccines.

The GM FluMist vaccines are based on non-GM attenuated human flu strains which have reduced ability to grow and cause disease. These attenuated strains are modified by incorporation of antigens from current circulating flu strains to provide protection against these flu strains.

How and where will patients be treated with the GM vaccines?

The GM flu vaccines would be nasally administered to up to 500 healthy adult male volunteers by qualified health professionals. The initial trial will take place in clinical facility in Brisbane, while later trials may also occur in Melbourne, Perth and Adelaide. Trial participants will be monitored from days 1 to 6 post-vaccination for adverse events, with a final assessment after 30-35 days.

Have these GM Vaccines been previously tested or used?

The clinical trials will study a new type of GM influenza vaccine (SAVE flu vaccines) which has not previously been tested in people.

FluMist vaccines were first marketed in the US as during the 2003/2004 flu season and in the EU (as Fluenz®) during the 2012/2013 flu season. They are currently authorised in the USA and Canada as FluMist Quadrivalent, and in the EU as Fluenz Tetra. The Regulator recently issued a DIR licence (DIR 137) for the Commercial supply of GM FluMist influenza vaccines in Australia.

What controls have been imposed for this trial?

The Risk Assessment and Risk Management Plan (RARMP) for this application concluded that the trial poses negligible to low risks to people and the environment. Licence conditions have been imposed to manage the risk, limit the scale and scope of the clinical trial, and restrict the spread and persistence of the GM virus. Control measures include limiting the GMOs that can be used in the clinical trials, administration of the GM vaccines only by trained medical staff, appropriate waste disposal, and requiring volunteers participating in the trial to take measures to limit the potential spread of the GMOs. Details of these licence conditions are set out in the RARMP.

Want more information?

Several documents relating to this decision are available on the [DIR 144](#) page of the OGTR website. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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