Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

November 2024

Summary of Licence Application DIR 210

Doherty Clinical Trials Ltd (DCT) has made an application under the *Gene Technology Act 2000* (the Act) to conduct a clinical trial using genetically modified organisms (GMOs).

Project Title	Clinical trials of controlled infection with seasonal influenza viruses
Parent organism	Seasonal human influenza virus A and B (including H1N1 and H3N2)
Genetic modifications	Recombinant influenza virus A and B produced using gene technology (reverse genetics) similar to naturally circulating wild type seasonal influenza viruses
Principal purpose	The initial aims are to evaluate the safety and infectivity of recombinant seasonal human influenza viruses in healthy volunteers. These GM viruses will then be used to assess the effectiveness of therapeutic drugs or vaccine candidates to prevent and control influenza infection.
Previous trials	The proposed study would be the first trial to be conducted with these GMOs in Australia.
Proposed limits and controls	
Proposed duration	5 years
Proposed locations	• DCT clinical trial facility located in Melbourne. • DCT Clinical trial unit laboratory support facility located in Melbourne. • WHO CCRI laboratory at DCT institute, located in Melbourne.
Proposed controls	• Trial participants will be isolated in secure rooms and will remain in isolation until they are no longer infectious. • Staff will wear appropriate personal protective equipment during and after GMO inoculation and the follow-up care of trial participants. • Trial participants will wear a surgical mask for 1.5 hours post-inoculation. • Any waste potentially contaminated with the GMOs will be adequately decontaminated. • Personnel conducting dealings with the GMOs will be vaccinated against influenza. • GMOs will be prepared, packed, transported, and administered by trained personnel. • GMOs will only be handled and stored within the secure PC2 laboratory at the DCT. • Activities involving the GMOs will be conducted in a Class II biological safety cabinet to minimise exposure from accidental aerosolisation.

The application

Influenza is an acute respiratory viral infection caused by influenza A or B viruses, with up to 650,000 deaths worldwide annually. For most healthy adults, seasonal influenza is a self-limited illness from which complete recovery is expected. Understanding the physiological and immunological responses of humans to these viruses is critical to develop vaccines and antivirals drugs for the control of influenza.

DCT is seeking approval to use genetically modified (GM) influenza viruses similar to naturally circulating influenza viruses to better understand influenza infection and test the efficacy of potential vaccines and therapeutic drugs. The GM influenza viruses are made using gene technology and are considered GMOs.

Healthy volunteers will receive a safe dose of the recombinant-influenza viruses within a clinical facility in combination with or without a potential vaccine or therapeutic drug.

The study will be conducted under strict ethical guidelines and safety protocols in an approved clinical trial facility, considering OGTR and good clinical practice guidelines. In addition, the applicant has proposed control strategies to restrict the spread and persistence of the GMO(s) in the environment.

The application is for limited and controlled release under section 50A of the Act, as the Regulator was satisfied that its principal purpose is to enable the applicant to conduct the trial, and the proposed limits and controls are such that consultation with prescribed experts, agencies and jurisdictions is not required at this stage.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed trial.

At this stage, the consultation RARMP is expected to be released for comment in late **December 2024**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR 195.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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