Australian Government
Department of Health
Office of the Gene Technology Regulator

12 April 2018

Summary of the Risk Assessment and Risk Management Plan (Consultation version)

for

Licence Application No. DIR 161

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application to conduct clinical trials using a genetically modified organism (GMO). It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act).

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed clinical trials pose negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed clinical trials. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application number:	DIR 161
Applicant:	Clinical Network Services (CNS) Pty Ltd
Project title:	A genetically modified respiratory syncytial virus (RSV) vaccine for use in clinical trials
Parent organism:	Respiratory syncytial virus
Modified genes and resulting modified trait:	L, N, P, M2-1 and SH genes of RSV (viral attenuation)
Proposed duration:	5 years
Proposed locations:	Clinical trial sites in Melbourne, Sydney, Brisbane, Adelaide and/or Perth
Proposed trial size:	Up to 350 adults of both genders
Primary purpose:	To conduct clinical trials assessing the safety, tolerability and efficacy of a genetically modified (GM) RSV vaccine.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms in adults and older healthy children, but is the most common cause of bronchiolitis and pneumonia among infants and younger children. While people of all ages can be infected, those at highest risk include premature infants, young children, the elderly and people who are immunocompromised. There are currently no available vaccines against RSV. The GM vaccine will be manufactured in the USA and imported into Australia. It will be administered by intranasal spray to up to 350 healthy adult volunteers at specialised clinical facilities located in Melbourne, Sydney, Brisbane, Adelaide and/or Perth. Blood and urine samples for analysis will be collected from trial participants over the course of the study.

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMO might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application (including proposed limits and controls) and relevant previous approvals. Both the short and long term impact are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GMO, potential for persistence of the GMO and the potential for recombination with other viruses. Potential harms that were considered in relation to these pathways included severe RSV disease and increased disease burden in people.

The principal reasons for the conclusion of negligible risks are the attenuated phenotype of the GMO in terms of reduced ability to replicate *in vivo*, the limited host range of RSV, and suitability of the controls proposed by the applicant.

Risk management plan

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft licence includes limits on the size, location and duration of the release, as well as controls to minimise the potential for the GMO to spread in the environment. In addition, there are several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.