Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of a genetically modified (GM) chimeric Orthopoxvirus as a cancer treatment

The Gene Technology Regulator is assessing an application from Medpace Australia Pty Ltd to conduct a clinical trial. The purpose of this clinical trial is to evaluate the safety and efficacy of a genetically modified (GM) chimeric Orthopoxvirus (known as CF33-hNIS) as a cancer treatment. The trial is proposed to take place at clinical trial sites and hospitals within Australia over a period of 5 years. Up to 18 trial participants would receive multiple doses of the cancer treatment.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via our website (search for DIR 192), or from the contacts below. Submissions should reference DIR 192 and be received by **18 August 2022**.

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