Australian Government
Department of Health
Office of the Gene Technology Regulator

NOTIFICATION OF APPLICATION

Receipt of licence application from Medpace Australia Pty Ltd for a clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 192) from Medpace Australia Pty to conduct a clinical trial with a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a treatment for solid cancers, that are locally advanced or have spread throughout the body. A summary of the application is posted on our website under News.

The trial is proposed to take place at clinical trial sites and hospitals within Australia over a period of 5 years. Up to 18 participants in Australia would receive multiple doses of the GM viral treatment over a period of 2 years, with the aim to evaluate the treatment's safety and efficacy.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. The RARMP will be prepared taking into account advice received from a broad range of experts, agencies and authorities, and relevant local councils, as specified in the *Gene Technology Act 2000*. This is expected to be released for public comment and advice from experts, agencies and authorities in July 2022. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the full application or the summary, please contact the OGTR and quote the reference number DIR 192.

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