

CLINICAL TRIALS: MEDICAL USE OF CANNABIS



The NSW Government has committed to clinical trials to further explore the use of cannabis and/or cannabis products in providing relief for patients suffering from a range of debilitating or terminal illnesses.

A clinical trial of cannabis derived products will be established for children with severe, drug-resistant epilepsy, through a partnership with the Sydney Children's Hospitals Network.

NSW Health will also work with the research community to assess interest in proceeding with trials in the areas of:

1. Adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting
2. Adults with chemotherapy-induced nausea and vomiting, where standard treatment is ineffective

The NSW Government will invest up to \$9 million over the next five years to support these initiatives. The trials will be led by the NSW Government. The Commonwealth and other Australian Governments have indicated their support for this NSW initiative.

Clinical trials take time and must meet national and international standards. These trials will seek to enhance available evidence to better understand the appropriate use of cannabis and cannabis derived products for medical purposes.

Children with severe, drug-resistant epilepsy

NSW Ministry of Health and the Sydney Children's Hospital Network have commenced preliminary development work on the research protocols for the paediatric epilepsy trial. The Network is best placed to manage the trial given it has established paediatric epilepsy units and outreach services across the state with links to national researchers in this field. Sourcing an appropriate cannabis-derived product suitable for use in the trial is a key step in the development process. The product must meet strict standards of production as well as the Therapeutic Goods Administration Clinical Trials standards. The trial is expected to start enrolling patients in 2016. Results of this trial should be available within two to five years.

Adult trials

It is expected that there will be a number of researchers and research networks interested in progressing clinical trials for adults. [Expressions of Interest](#) close 27 February 2015. Finalising the expression of interest, including assessment of proposals from interested researchers and sourcing an appropriate cannabis-derived product, should allow the trial to commence in 2016. More information on the application process to conduct clinical trials is available on the [NSW Health website](#).

Expert panel to guide the trials

An expert panel chaired by the NSW Chief Health Officer will continue to advise the NSW Government throughout the trial period. The Panel comprises experts in cancer medicine, palliative care, clinical epidemiology and research design, adult neurology, paediatric neurology, medicines regulation, clinical pharmacology, and addiction medicine.

Becoming a trial participant

All clinical trials need to be scientifically valid so that doctors and researchers can rely on the results to help them treat their patients. This means that trials have strict eligibility criteria.

Those adults certified as having debilitating or terminal illnesses and those who are on the [Terminal Illness Cannabis Scheme Register](#) may be eligible for consideration to become a trial participant. Because of the nature of any individual's medical condition sometimes not all those interested in participating may be suited to the trial.

Once the scope of each trial is finalised, further information on eligibility will be available. Recruitment to clinical trials generally occurs through:

1. open advertising through patient support groups, newspapers and websites
2. invitation by a treating clinician for patients who may benefit in participation
3. individuals contacting the researchers directly to determine eligibility.

For reputable clinical trials taking place in Australia visit www.anzctr.org.au

The Terminal Illness Cannabis Scheme

The NSW Government has developed the Terminal Illness Cannabis Scheme to provide adults with a terminal illness who choose to use the cannabis for symptom management and their carers with greater piece of mind.

The Terminal Illness Cannabis Scheme provides guidelines for NSW police officers to assist them in determining appropriate circumstances in which to use their discretion not to charge adults with terminal illness who use cannabis and carers who assist them.

More information about the Terminal Illness Cannabis Scheme is available on the [NSW Government website](#).

Cannabis use

Cannabis remains an illegal and potentially harmful drug and is not approved as a medicine by the Therapeutic Goods Administration. Adults with a terminal illness who choose to use cannabis do so at their own risk.

More information

Information about cannabis and cannabis products is available on the [NSW Health website](#).