

## New Zealand aims at early phase and proof of concept trials

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New Zealand has held a clean track record with early phase and proof of concept trials and has maintained accuracy in the compilation of clinical data. The straightforward regulatory system in the country, with one approval covering all sites, gives New Zealand the much-needed boost. The regulatory framework for New Zealand is based on European and American systems, and the Good Clinical Research Practice guidelines based on International Conference on Harmonisation and Good Clinical Practice (ICH-GCP).

The New Zealand Association of Clinical Research (NZACRes), that promotes clinical research in the country, has developed standard agreements for both clinical trial research and indemnity and compensation. Gaining approval from the Ministry of

Health's (Medsafe) Standing Committee On Therapeutic Trials (SCOTT) for a trial in New Zealand takes a maximum of 45 days. This approval is required for non-registered drug formulations. Alongside, the company can submit an Ethics Committee (EC) application. Once SCOTT issues a 'Recommend for Approval' certificate, the final approval is sanctioned immediately after EC approval is obtained.

Further, for human trials that might have legal and ethical consequences, a Health & Disability Ethics Committee (HDEC) approval is required. As per the Health Strategic Initiatives Review Committee, the country's aggregate annual clinical trial revenue is less than \$30 million; Australia in comparison generates about \$450 million from pharmaceutical clinical trials. Further, the country's investment in science research and development had been below the Organization for Economic Co-operation and Development (OECD) average for public expenditure at about 0.59 percent of GDP and one-third of the OECD average of 0.5 percent of GDP.

Today, over 550 trials are being recruited in New Zealand and the private and public expenditure on health in the country is over \$18 billion. Acting on the recommendations by the Health Select Committee, the ethical review process of trials has been simplified and streamlined to promote collaboration between government departments to coordinate the system. Also, a national health research action plan is underway to boost innovation and commercialization. In addition, the country is developing a framework for clinical trial research throughout district health boards, to be facilitated by a hub.

This year, the government invested \$50,000 to launch the [New Zealand Clinical Trial Portal](#) to update the public, healthcare providers and industry partners about health research underway in the country. The National Ethics Advisory Committee is currently working to assess the impact of these changes on the review of health and disability research ethics.