IMPROVING THE NZ ENVIRONMENT TO SUPPORT INNOVATION THROUGH CLINICAL TRIALS

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Science R & D Innovation

Speech from the Throne (Prime Minister, Helen Clark) 2005 ‘Science critical to driving New Zealand Economy’

Prime Minister John Key 2009 ‘Science and innovation will be at the centre of my government’

	NZ	OECD Average
Public Investment R & D	0.54 % GDP	0.68% GDP
Private Investment R & D	0.44% GDP	1.5% GDP

2010 Government sector funded $1,117 million of research and development. This is an increase of $205 million (22%) on 2008.

Improving NZ Environment To Support Innovation Through Clinical Trials

WHY AN INQUIRY?

2009 -

- Professor Shaun Holt – criticises New Zealand ethics system as slow and bureaucratic.
- Professor Tim Dare – 'NZ health ethics system up with world standards'
- Rudd Government Taskforce – 'to make Australia the best place in the world to carry out clinical trials'.

2010 -

- UK Academy of Medical Science Report – 'a new pathway for the regulation and governance of health research'

New Zealand aims to make its environment to carry out clinical trials and support innovation as good if not better than anywhere in the world.

Improving NZ's Environment to Support Innovation Through Clinical Trials in NZ

CURRENT ENVIRONMENT CLINICAL TRIALS

Strengths

- World class education, university and health system.
- Dedicated clinical research faculty – net worked locally (CTNZ) and internationally.
- Sustained quality, effective recruitment, desire to innovate.
- Robust high quality ethics system.
- Stable population mix, identifiable personal health number.

Weaknesses

- Bureaucratic, unwieldy ethics system.
- Uncoordinated district health boards.
- ? Pharmac

Improving NZ's Environment to Support Innovation Through Clinical Trials in NZ

Terms of Reference (Inquiry)

- Coordinated, nationwide approaches to clinical trials
- Streamline ethics approval systems
- National patient referral networks
- Removal unnecessary barriers
- How to benefit the NZ innovation system, health system and economy

Rationale – Multibillion Dollar Industry

- Good for patients, standards, health systems, scientists, attracting top clinicians
- Good to support biopharmaceutical, medical device and functional food industries in New Zealand – good for the economy

Pharmaceutical Clinical Trial Activity – estimated $40 million per year

Medical Technology Association of NZ (MTANZ)

Medical Technology Industry



Annual turnover $1.3 billion 2008/09

- ($950 million public spend, $350 million private health spend).

Export income $333 million 2007/2008 - $600 million (2010)

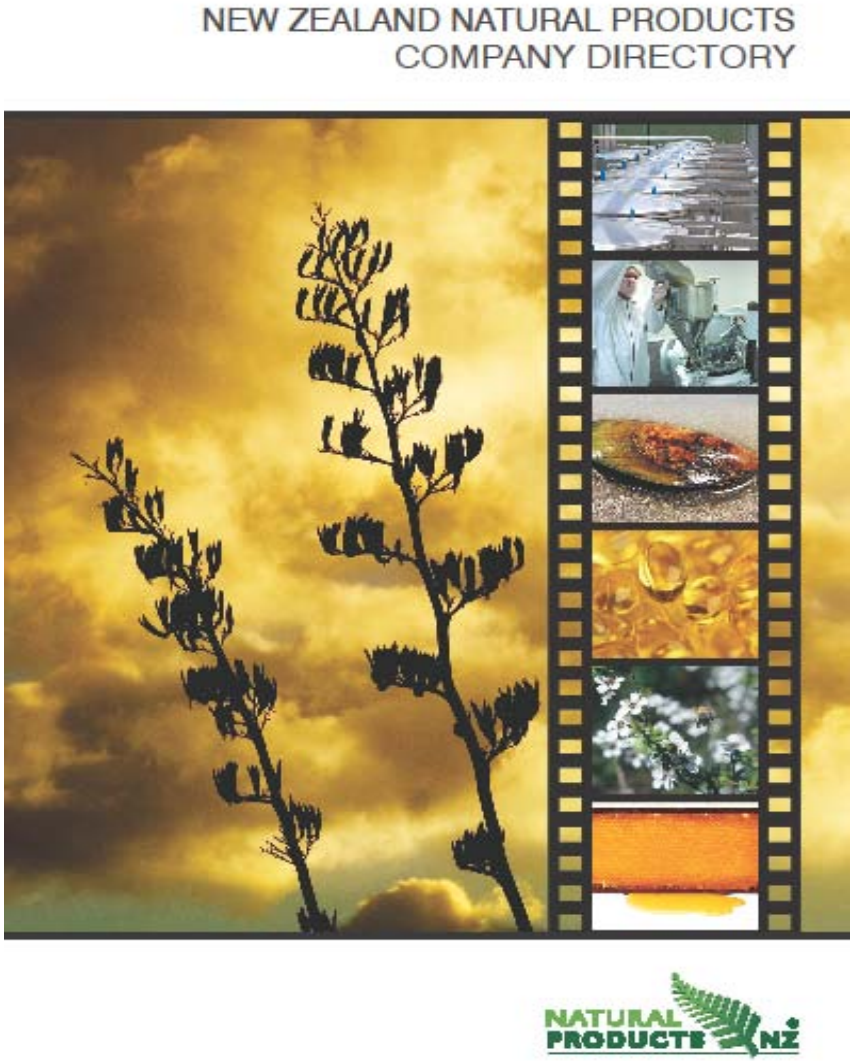
- Aim $1 billion by 2012
- Employs more than 6000 people

Research investment $56.5 million 2007/2008

Orthopaedic Synergy (orthopedic devices)

Fisher & Paykel Healthcare (respiratory devices, sleep apnoea).

Dynamic Controls (electronic wheel chairs and scooters).



Natural Products

- Exports 2011
- $1 billion NZ

Simplify and Streamline Ethical Review Process

By 1 July 2012 Government agrees to:

- Updating and streamlining the fragmented procedural guidelines of Ethics committees.
- Shorten and simplify application forms
- Develop an electronic (online) application and centrally managed system.
- Introduce internationally competitive timeline for HDEC review, require regular reporting.
- Medsafe aims to decide all applications for ‘section 30’ (new medicines) within 25 days.
- Expedited review for low risk trials
- Establish comprehensive standardised operating procedures
- Remove duplication and ambiguity
- Application forms to be short and simple (developed by mid January 2012)

Ministry of Health, Health Research Council of New Zealand and Ministry, Science and Innovation

Progressing development of a National Health Research Strategy (clinical trials should be included).

Collaboration between Ministry of Health, Science and Innovation, Economic Development and New Zealand Trade and Enterprise.

- Work is already underway
- Work progressing for establishment of a National Health Innovation Hub (connecting the health system with industry in the commercialisation of products and services).
- On-going progress with New Zealand Trade and Enterprise action plan to establish New Zealand as an intelligent niche player in the clinical trials industry.

District Health Boards

Government agrees to:

- Remove duplication in ethics review process
- Support a standard indemnity agreement for ‘form B’ trials
- Review of operational policy and consider adoption of NZ Association of Clinical Research standardised contracts.
- Assessing proposition of a national framework for clinical research.
- Work to improve coordination across the DHB’s.
- The National Health committee will manage an innovation fund which will support trialling, testing, or assessment of new technologies.

That New Zealand becomes as good as, or better than, anywhere to carry out clinical trials

Government

- Committed to science and innovation as one of six pillars of economic growth.
- Demonstrated investment commitment to science, research and development by 22% increase between 2008 and 2010.
- Committed to low tax, low compliance regulatory environment, with flexible labour market.

Clinical trials

- Committed to achieving highly efficient (speed to start) cost effective, safe systems that have regard to meeting enrolment targets, high quality data, clinical expertise, measurable performance metrics, user friendly and coordinated public system. Avoid crowding out, allow private system to thrive.
    - Pharmaceuticals
    - Medical Technologies
    - Functional Foods
    - Bioactives
    - Biologics

Can we do it? Yes we can!

Ernest Rutherford

Maurice Wilkins 1999

Paul Hutchison, Alan MacDiarmid and Hon Nick Smith

Can we do it? Yes we can

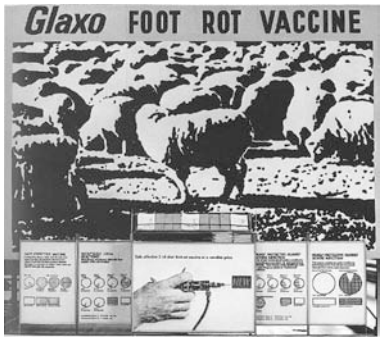
Glaxo Smith Kline

2010 Turnover NZ $54.8 billion

Research and Development spend NZ $7.64 billion, 14% turnover

Bunnythorpe 1900

London 1921



Glaxo Foot Rot Vacinne

New Zealand's most famous clinical trial

Sir Graham Liggins

'Lambs, lungs and babies lives'

Steroid treatment for prematurity

His steroid discovery paper was praised for its meticulous randomised control design.