

Submission by



SUBMISSION

to the

NEW ZEALAND PARLIAMENT

on the

Submission on the Health Reforms (Pae Ora) Bill
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BIOTECH NZ SUBMISSION ON THE HEALTH REFORMS (PAE ORA) BILL

INTRODUCTION

BioTech New Zealand (BioTechNZ) welcomes the opportunity to make this submission to the Health Reforms (Pae Ora) Bill

BioTechNZ is a membership-funded organisation. A diverse range of members share a desire to maximise the ways that biotechnology can address many of New Zealand's (and the World's) agricultural, environmental, industrial and health problems.

BioTechNZ furthermore connects innovators, investors, regulators, researchers, social entrepreneurs and interested public. We also help raise awareness and increase understanding of biotechnology to enable our nation to embrace the best opportunities biotech offers to us daily, helping us live better, healthier and more productive lives.

We take a practical, but information and evidence-based approach, focusing on harnessing the opportunities and addressing the issues. We draw on the active contributions of all members. In 2018, BioTechNZ joined TechNZ, the peak body for New Zealand's technology ecosystem.

"The Purpose of this Bill provides for a new structure and new accountability arrangements for the publicly-funded health system, in order to protect, promote, and improve the health of all New Zealanders. BioTechNZ are fully supportive of this statement, and see the Pae Ora legislation as a once in a generation opportunity to improve the New Zealand health system.

However, this bill does not realize the opportunities available to put New Zealand at the forefront of the healthcare revolution. We recommend a stronger focus on research: it is the single most important way in which we improve our healthcare – by identifying new means to prevent, diagnose and treat disease.

We urge the government to seize this unique opportunity to set a bold and ambitious vision for the future and legislatively recognise the importance of health research and innovation, as this will underpin health outcomes for all New Zealanders. The UK Government has recently taken this approachⁱ.

BioTechNZ and its members are highly supportive of the content within the submission from **New Zealanders for Health Research**.

WHAT IS MISSING IN THE HEALTH REFORMS (PAE ORA) BILL

1) Research and Development

The first sentence in the Minister's forward for the New Zealand for Health Research Strategy 2017-2027 was "This first New Zealand Health Research Strategy brings together science, health, research and innovation to form a more **cohesive system that will have the greatest impact on the lives of New Zealanders**". Health research is central to New Zealand's national innovation system. The Government, the tertiary education sector, the health sector and private enterprise all have particular roles in making it successfulⁱⁱ.

Following are the four strategic priorities that set the direction for the health research and innovation system, and that collectively will increase the impact of health research:

1. Invest in excellent health research that addresses the health needs of all New Zealanders.
2. Create a vibrant research environment in the health sector.
3. Build and strengthen pathways for translating research findings into policy and practice.
4. Advance innovative ideas and commercial opportunities.

We recommend that these priorities be incorporated into the Health Reforms (Pae Ora) Bill.

However, a simple word search of the Bill for key phrases yielded the following results: “**New Zealand Research Strategy**” appeared 0 times in 0 clauses, “**clinical trials**” appeared 4 times in 4 clauses, “**Research**” appeared 7 times in 4 clauses, “**innovation**” appeared just once in 1 clause. The emphasis of this Bill is not focussing on the underlying issues, merely the re-structure of the organisation, however, health research is the single most important way in which we improve our health and healthcare – by identifying and implementing the best means to prevent, diagnose and treat conditions for all New Zealanders.

Unfortunately, New Zealand’s health innovation system can be characterised as disjointed at best. There are numerous sources of health research funding and activity, industry and sector intervention, business development funding and healthcare providers but no coherent means for activity in one area to link through to the next. New Zealand’s health system falls short when it comes to both discovering new interventions and translating the results of health research into practice, policy and better health outcomes.

Chief Science Advisor at the Ministry of Health, Professor Ian Town, says now more than ever New Zealanders are aware of the importance of scientific evidence and the vital role of clinical research in finding solutions for the many health challenges we faceⁱⁱⁱ.

Moving forward, we need to ensure we focus our attention and our efforts on research that aims to address the most pressing population health needs for people across New Zealand, while continuing investigator-driven research to help generate new and innovative delivery models.

Recommendations:

1. The Health Research Council should be articulated in the Bill as playing a greater role in the translation of health research into practice, policy and better health outcomes.
2. With the COVID-19 pandemic New Zealand has had greater involvement with multinational corporations (MNCs) and we see that part of the mandate for the Health Research Council is to create an attraction programme that makes New Zealand an attractive place for MNCs to partner and actively engage with our science ecosystem.

2) Clinical Trials

Clinical trials have been shown to improve the quality, effectiveness and efficiency of healthcare delivery and health outcomes for New Zealanders.

Clinical trials conducted within clinical trials networks are a mechanism to enhance: the relevance and quality of research; reach of the research process; translation of evidence into practice and policy; equity of healthcare delivery and health outcomes; development of new health innovations; culture of research in the health sector; and the skill and sustainability of the workforce.

Furthermore, clinical trials research can drive economic impacts (both as an export earner and through improving cost effectiveness of health care) and strengthen the international competitiveness of New Zealand. Realising the potential of clinical trials research in New Zealand is

aligned with the New Zealand Health Research Strategy 2017-2027 and the New Zealand Health Research Prioritisation Framework^{iv}

One indicator of how well the country's health innovation sector has been performing is commercially funded clinical trials of new interventions, including health technology, devices and new therapies^v. New Zealand for Health Research's 2020 *Briefing for the Incoming Minister* included: that there has been limited overall but latterly declining growth in the number of commercially funded clinical trials undertaken in New Zealand; drug trials are showing no growth; the number of trials funded by international pharmaceutical companies which operate in New Zealand has fallen significantly; and New Zealand has been losing its share of the combined Australia-New Zealand market.

This is a huge concern as clinical trials play a vital role in answering questions about how to manage a particular disease, with trials of new drugs or vaccines only a small component of this. "This disparity is compounding existing health inequities given the clear evidence that participation in clinical trials improves health outcomes, irrespective of what intervention participants are randomised to receive," says Professor Bloomfield^{vi}.

Why are clinical trials important in our health system?

- Concerns about patient inequality. The number of New Zealanders participating in clinical trials – particularly those living in rural communities and Māori and Pasifika – to ensure equitable access to the latest and most cutting-edge healthcare.
- Since clinical trials provide access to novel therapies years before they become available on the open market, some physicians may be curious about participating in the clinical trial process.
- by delivering more streamlined and more efficient clinical research –allows more people to participate and to access new or improved treatments, technologies and techniques.
- Enable our health system to translate evidence more rapidly and consistently into clinical practice for the benefit of all New Zealanders.
- NZ often doesn't have standard of care so the control arm in a clinical trial is better than their current treatment.
- Obtaining this information, alongside information from international best practice, is essential to underpin recommendations to inform policy for clinical trials infrastructure in New Zealand and to contribute to the development of a sustainable, nationally coordinated and equitable clinical trials enterprise in New Zealand.

Clinical trials enable our health system and health professionals to continuously learn and get better at what they do. However, many health providers are unable to conduct clinical trials, simply because they do not have the expertise, networks, and systems in place. And where trials are taking place within the health system, they can be quite disconnected from healthcare delivery.

Recommendation:

- 1) Clinical trials need to be embedded into the Health Reforms Bill.
- 2) As Clinical trials are not well understood by the public, it should be included in legislation that the health authorities have the funding to drive education campaigns around increasing the participation in clinical trials, to ensure equitable access to the latest and most cutting-edge healthcare.
1. That there are key performance indicators within the senior management, that there is a clear expectation around embedding clinical trials and the clinical trial networks into everyday patient care, where it is seen to provide education to our health providers, allowing them the time to upskill in current therapeutic, medical devices, networks and systems in order for patients to participate in a clinical trial.

- a. Which will strengthening capacity in the clinical health research workforce, to improve clinical services and care and attract and retain top clinicians in New Zealand.
2. Create a coordinated national clinical trials system across New Zealand embedding into our health system, with all the supporting systems required.
3. Harnessing the power of multi-centre and multi-national clinical trials data to improve the management of health conditions in a timely manner for New Zealanders.

3) New Innovations

This bill should recognise the role of technology and innovation for the future of New Zealanders, as it can drive economic growth by improving efficiency and increasing productivity, as well as optimizing patient outcomes. The Health Reforms (Pae Ora) Bill should also link into the Digital Strategy for Aotearoa^{vii}.

1. Digital and Medical Device Technologies

The pandemic has created opportunities for New Zealand businesses to better engage with overseas markets, given the increased uptake of digital technologies. New drugs, diagnostic methods, drug delivery systems, and medical devices offer the hope of better treatment and of care that is less costly, less disruptive and less painful. For example, to name a few:

- Telemedicine, accessing patients in remote areas
- implanted sensors can help patients monitor their diseases more effectively.
- IT innovations that connect information in the health care system which can vastly improve quality and lower costs.

2. New Human Therapeutics

Gene modification is increasingly becoming the subject of health research initiatives, whether that be through the application of CRISPR techniques for addressing genetic disorders, or the development of new medicines such as vaccine based anti-cancer CAR-T therapies currently being pioneered by the Malaghan Institute of Medical Research.

New Zealand's current GMO legislation is stifling research in this area and BioTechNZ highlights this in the submission made on the Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill, as noted by the Royal Society in August 2019, organisms can no longer be categorised as 'genetically modified' or 'not-genetically modified' and this is why BioTechNZ urges the Committee to recommend a substantive legislative review of HSNO and genetic technologies.

The Environmental Protection Agency processes for approving clinical trials of genetically modified organisms based therapies was also identified as a key issue by participants as a barrier to the conduct of clinical trials.

Recommendations

- 1) Legislatively imbed health research as an essential component to reform the health system.

4) SPECIFIC RECOMMENDATIONS RELATING TO THE BILL

Amendments are indicated in **red**.

At section 3 insert new clause (d)

The purpose of this Act is to provide for the public funding and provision of services in order to—

- (a) protect, promote, and improve the health of all New Zealanders; and
- (b) achieve equity by reducing health disparities among New Zealand’s population groups, in particular for Māori; and
- (c) build towards pae ora (healthy futures) for all New Zealanders; and
- (d) ensure New Zealanders benefit from a world-class domestic health research ecosystem.

At section 7 insert new clause (f) below clause (e) at subsection 1

1. For the purpose of this Act, the health system principles are as follows:

- (f) The health system should ensure New Zealand has globally significant health research and innovation, including by—
 - (i) ensuring that legislation and regulations, across government, to facilitates, promotes and enables an ethical health research ecosystem; and
 - (ii) embedding health research into care and treatment; and
 - (iii) undertaking health research where people are by engaging with under-served communities, especially Māori and Pasifika; and
 - (iv) developing and enhancing digital platforms to deliver health research delivery; and
 - (v) working seamlessly across the public and private systems.

5) REFERENCES

ⁱ [Saving and Improving Lives: The Future of UK Clinical Research Delivery - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery)

ⁱⁱ [nz-health-research-strategy-jun17.pdf](#)

ⁱⁱⁱ [Study to get more Kiwis participating in clinical trials | Health Research Council of New Zealand \(hrc.govt.nz\)](#)

^{iv} [The New Zealand Health Research Prioritisation Framework \(hrc.govt.nz\)](#)

^v [DR-040-New-Zealanders-for-Health-Research.pdf \(productivity.govt.nz\)](#)

^{vi} [Study to get more Kiwis participating in clinical trials | Health Research Council of New Zealand \(hrc.govt.nz\)](#)

^{vii} [NZTech-submission-Towards-a-Digital-Strategy-for-Aotearoa.pdf](#)