Towards a national equitable and sustainable clinical research infrastructure for Aotearoa New Zealand

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ABSTRACT

Clinical trials are a critical element of a modern, high-functioning, learning healthcare system. Clinical trials provide access to novel, as yet unfunded treatments, and deliver cutting-edge healthcare. Evidence from clinical trials ensures appropriateness of healthcare, allows disinvestment from practices that are found not to improve outcomes or be cost-effective, and supports the introduction of new approaches, all of which leads to improvement in health outcomes. In 2020, Manatū Hauora – Ministry of Health and The Health Research Council of New Zealand funded a project to understand the current state of clinical trial activity in Aotearoa New Zealand and to propose the infrastructure required to support equitable clinical trial activity, in order to ensure that trials benefiting from publicly funded infrastructure are responsive to the needs of New Zealanders and ultimately enable equitable delivery of the best healthcare we can achieve to all New Zealanders. This viewpoint reports the process that was undertaken to develop the final proposed infrastructure and the rationale for the approach. The restructuring of the Aotearoa New Zealand health system into Te Whatu Ora – Health New Zealand and Te Aka Whai Ora – Māori Health Authority that will both operate hospital services and commission primary and community healthcare at a national level provides the ideal opportunity to integrate and embed research into Aotearoa New Zealand's healthcare system. Integration of clinical trials and research more broadly into the public healthcare system will require a significant shift in the culture within our healthcare system. Research must be recognised and promoted as a core activity for clinical staff at all levels of the healthcare system, rather than something to be tolerated or even hindered. Strong leadership will be required from the top of Te Whatu Ora – Health New Zealand down to ensure the required cultural shift to recognise the value of clinical trials to all aspects of the healthcare system, and to grow capability and capacity of the health research workforce. The investment required by the Government to implement the proposed clinical trial infrastructure will be substantial, but now is the ideal time for investment in clinical trials infrastructure in Aotearoa New Zealand. We urge the Government to be bold and invest now to ensure the benefits can be reaped for all New Zealanders in years to come.

Clinical trials are a core element of a modern, high-functioning, learning healthcare system. Clinical trials can provide access to novel, as yet unfunded treatments, and deliver cutting-edge healthcare. The evidence generated by clinical trials is ultimately used to improve our health services, from public health and prevention interventions, through to specialised medicines and novel devices, to delivery of care by increasing the efficacy and efficiency of care, thereby bettering the health of New Zealanders.

Aotearoa New Zealand does not invest as effectively as it could, and should, in clinical trial research, nor in health research generally when compared to Australia, the United Kingdom and the United States.[1,2] Thus, we do not realise the significant potential benefits of clinical trial research for the people of Aotearoa New Zealand. Current clinical trial benefits are distributed inequitably because of the health system's fragmentation and rigidity, a lack of understanding of the benefits of clinical trials, and because clinical research is not embedded as part of a learning healthcare system. To respect Te Tiriti o Waitangi and meet the Crown's obligations as a treaty partner, it is critical that we have reliable clinical evidence of the efficacy and safety of healthcare interventions for Aotearoa New Zealand's population, especially Māori. Realising the potential of clinical trials research in Aotearoa New Zealand is aligned with the New Zealand Health Research Strategy 2017–2027 (https://www.health.govt.nz/publication/new-zealand-health-research-strategy-2017-2027)

and the New Zealand Health Research Prioritisation Framework (https://www.hrc.govt.nz/resources/new-zealand-health-research-prioritisation-framework).

In 2020, Manatū Hauora – Ministry of Health (MoH) and The Health Research Council of New Zealand (HRC) funded a project to understand the current state of clinical trial activity in Aotearoa New Zealand and to propose the infrastructure required to support equitable clinical trial activity, in order to ensure that trials benefiting from publicly funded infrastructure (including commercial trials) are responsive to the needs of New Zealanders and ultimately enable the equitable delivery of the best healthcare we can achieve to all New Zealanders. Herein, we outline the process undertaken to determine the broad infrastructure required for clinical trials in Aotearoa New Zealand and our proposal for the way forward.

Methodology

The scope of the project was defined by the HRC and MoH as outlined in the Request for Proposals (RfP) (Table 1). This project was independent research led by the authors and involved a diverse group of clinical researchers from a range of backgrounds and disciplines. It involved a specific Rōpū Māori, a Pacific advisory group, and a consumer group. The programme leads consulted a group of international researchers and reported to an expert steering group appointed by the MoH and HRC. There were two clearly defined areas for focus outlined in the RfP, namely systems and data (Table 1). Activity within the project was divided into five workstreams: clinical trial activity, infrastructure and networks, data systems and curation, equity and consumer engagement, prioritisation, knowledge translation and implementation, and workforce capability.

Within the two focus areas, systems and data, the research first sought to provide an assessment of the current state of clinical trial activity in Aotearoa New Zealand. We collected information from the Australian New Zealand Clinical Trials Registry (ANZCTR), conducted a survey of researchers, carried out 58 individual and group interviews, and consulted with the Rōpū Māori, Pacific advisory group, and consumer group. Two pieces of work—a synthesis of international best practice and Kaupapa Māori analysis—were also undertaken. The current state findings were reviewed by stakeholders in an all-day "world café", facilitated and attended virtually due to COVID-19 restrictions. The 72 attendees included consumer representatives, primary care (including rural general practitioners), community trialists, pharmaceutical and medical device companies, Māori, Pacific, and hospital-based clinical trial researchers, to name a few. The workshop provided deep insights into what the ideal clinical trials infrastructure for Aotearoa New Zealand would look like, and if implemented, what benefit should come from this unique opportunity in the health sector.

The findings from the world café workshop, alongside previously gathered current-state material, were used to refine and develop the clinical trial infrastructure options by the project team. A Delphi survey was undertaken to test the criticality of the options and whether stakeholders considered they were necessary or critical for inclusion in any proposed infrastructure. The 347 participants included the study investigators, Māori, Pacific, consumers, and industry and healthcare stakeholders. A key modification of the Delphi method for the purposes of this project was that investigators reserved their right to include infrastructure options even if not deemed critical by the stakeholders, which is particularly important for areas of the infrastructure that should be a "given," such as Māori data sovereignty mechanisms, embeddedness of Te Tiriti within the clinical trial system, and Māori co-governance and input into operational matters and priority.

Conducting the Delphi survey helped capture the viewpoints of the diverse and varied stakeholder groups. Being an iterative process, it assessed the level of agreement and provided a mechanism for resolving disagreement to build consensus around the proposed options. During the first round, participants were able to submit options that might have been missed; the group voted on the additional options in the two remaining rounds. In each round, stakeholders were given a list of potential infrastructure options and asked to rank them on a scale of 0 (not important) to 9 (critical) in terms of how critical the option was for inclusion in the proposed infrastructure (i.e., how necessary it is for this option to be included for the system to be successful). After each round, the aggregate results were presented back to the stakeholders. There was the opportunity for stakeholders to provide feedback to enable any necessary clarification of the

options within the next round and to express interest in attending a consensus meeting to finalise the results of the Delphi. At the end of the three rounds, conducted between October 2021 and February 2022, it became clearer where there was consensus for critical inclusion of infrastructure options and where there was not. Consensus for inclusion was determined when >70% of respondents had voted a score of 7 out of 9 or higher **and** <15% of respondents voted a score of 3 out of 9 or lower. For consensus for exclusion, the criteria were reversed. A further consensus meeting was held after the third round by video-conference as a final test of consensus for critical inclusion of infrastructure options, and to discuss and finalise a decision on the options that did not reach a consensus.

The findings of the Delphi survey were categorised by respondent group (Māori, consumer, and general, where general refers to all other stakeholders) to compare the perceptions of criticality between groups. This categorisation was of particular importance for understanding Māori respondents' perceptions and whether they differed from the perceptions of the rest of the stakeholders.

Based on the Delphi survey results and data from the previous phases, the project team outlined a high-level roadmap of the steps required to transform the current state to the desired future state. Critical factors considered the needs to best support a sustainable and nationally coordinated clinical trials enterprise in Aotearoa New Zealand and contribute to improved and more equitable health outcomes for New Zealanders.

Key findings from the current state analysis

Aotearoa New Zealand's healthcare system does not generally have a strong research culture, notwithstanding individual examples of excellence. Research is not embedded within everyday practice nor within the organisational structure which often does not facilitate research activity; indeed, in many cases, the system is a barrier to the conduct of research. The clinical research workforces lack support. Investigators within the healthcare system rarely have time spent on clinical research acknowledged or accommodated and often are not supported by a functioning health research ecosystem within their place of work. The Māori and Pacific clinical research workforces are particularly thinly stretched, with barriers to development and support for those wishing to pursue a research career.

Despite the challenges, clinical trials are being conducted in Aotearoa New Zealand in a wide range of settings, with a wide range of goals, in a variety of ways, at all phases of medicine development and evaluation (discovery and development of medicine, preclinical research, clinical research) as well as in public health, functional foods, biotechnology development, devices, and trials to improve standards of routine care. In some cases, clinical trials are undertaken principally to provide access to medication, rather than primarily for a research goal. Clinical trials being undertaken in Aotearoa New Zealand range from small (<50 participants) to very large (>1,000). There are examples of good access to key infrastructure, such as statistical expertise, or experienced research nurse support, but that access is very patchy. The lack of infrastructure is an important barrier to undertaking research, to development of a sustainable research workforce and to equitable access to linical trials for patients across the motu. Existing clinical trial networks provide critical support for researchers, enabling high-quality success, but they are fragile and not resourced sustainably. Accurately costing and adequately funding clinical trials and clinical trial development is difficult, and the ability to conduct a long-term clinical trial (>3 years) within existing funding caps is problematic. The variable nature of research capability, capacity, and infrastructure across Aotearoa New Zealand, together with the requirement for multiple approvals at different sites, means it can be challenging, time-consuming and expensive to recruit multiple sites to clinical trials. These factors often lead to recruitment that lags behind overly ambitious targets and the need for multiple applications for funding to support a single trial.

Of particular importance, there is a gap in partnership with Māori, both in the design and conduct of individual trials, and in the wider infrastructure of trial activity, including in the management of data and tissue samples with appropriate tikanga. Information needs are changing, data governance processes are diverse and often not systematic, and there is little guidance on data sovereignty. There is a need for clinical trial methodologies and conduct to be more responsive to Māori needs, and more culturally safe.

Table 1: Areas of focus of the project from the RfP.

Areas of focus
Systems Community/organisational/regional/national and international systems and networks that improve **coordination of, and collaboration for, Aotearoa New Zealand clinical trials**, and subsequent knowledge transfer.
Description
• Pathways/models for identifying research that reflects clinical **priorities** of the health sector and public/patients. • The reach and capability of clinical trials **networks**, both Aotearoa New Zealand-only networks and Aotearoa New Zealand arms of multi-national networks, particularly with respect to reach across disciplines, geographical regions/unit, levels of the health system, and current and potential future capabilities and sustainability. • Clinical trial **site and coordinating centre** structures, functions, and facilities for public-good and commercial clinical trials (conducted in the public healthcare system). • **Workforce** capabilities that are specific to the conduct of public-good and/or commercial clinical trials (conducted in the public healthcare system), above normal service delivery personnel, to include identifying roles or capabilities that would be better centralised or viewed as shared services. • Systems for a national equitable approach to patient/participant **recruitment** for public-good and commercial trials (conducted in the public healthcare system). • **Culturally appropriate involvement** of consumers (including Māori) in the trial process, including in trial design, monitoring, and as participants. • Processes for **knowledge translation**, including audience-specific pathways for patients, service providers, and decision makers (managerial or policy), including implementation (as appropriate) of trial results (from Aotearoa New Zealand and international research).
Data Clinical quality registries, electronic medical records, administrative datasets, research databases and research-supportive IT systems.
Description
• Identify and address data silos and/or optimise **interoperability** in a clinical trial setting. • Availability and adequacy of **routinely collected data** for public-good and commercial clinical trials throughout the trial lifecycle, and associated issues, such as ethical aspects related to use of routine data. • Types of and standards for clinical research **databases** including Australasian and international. • Management and availability of data outputs from public-good research for **further use**, with specific consideration of cultural and ethical aspects of data use. • The use of **clinical trial management systems** to aid efficiency and effectiveness.

Table 2: Overarching recommendations.

Overarching recommendations
National level essentials
• National leadership at the executive level within HNZ and the Māori Health Authority. • Strategies to increase Māori and Pacific clinical trials workforce. • National approach to developing relationships with Māori to ensure co-design and partnership. • National approach to data governance, curation, sharing, and Māori data sovereignty. • National resource of people and information to support clinical trial activity. • National approach to consumer partnership, including education and training of consumer research partners. • National support for clinical trials networks and infrastructure.
Regional level essentials
• Consumer engagement support. • Support with Māori community engagement and Māori health advancement. • Local/regional activity that identifies clinical trial activity of specific importance to local communities, including Māori. • Provision of support in the following areas: statistics, health economics, ethics and regulatory approvals, finance and budgeting clinical trials, database design provision and maintenance, and a 24-hour randomisation service, including unblinding.
Recommendations
• The national clinical trials infrastructure must be underpinned by principles of Te Tiriti and developed in co-governance with Māori. • The responsibility for ensuring high-quality research activity must be woven into the job descriptions of all senior clinical leaders in Health NZ and the Māori Health Authority. There must also be targeted measures of accountability for these senior clinical leaders. • There must be an adequately resourced National Research Office for Te Whatu Ora – Health New Zealand, co-governed with the Māori Health Authority, with research leadership at the executive level of the organisations. While this function exists within the context of health research policy leadership from Manatū Hauora – Ministry of Health, in order to envisage possible gains it is essential for Te Whatu Ora – Health New Zealand to have research leadership at the operational level. • There should be a National Clinical Trial Infrastructure Centre with expertise from across the country that will provide leadership, governance, expertise, and overall, high-level national support and coordination of trial activity, including the support of clinical trial networks in Aotearoa New Zealand. • There should be Regional Clinical Trial Coordinating Centres around the country that, between them, provide the necessary expertise to support clinical trials. Each of these centres will support trial development and conduct across regional nodes to ensure equity of access for both researchers and participants, and will collaborate with other centres to support local, regional, national, and international trials.

Table 2 (continued): Overarching recommendations.

Overarching recommendations
Recommendations
• There should be sustainable and systematic networks for Māori and Pacific researchers to support Māori and Pacific research communities in a regular and coordinated way, in accordance with the recommendations and priorities identified above, along with active development and support for the Māori health research workforce to meet commitments to Te Tiriti and to reduce inequities in health. • Partnership with Māori and local Māori communities at every level, including trial implementation and national infrastructure. • Supporting Te Ao Māori methods/priorities and engagement with researchers and communities. • Embedding Māori data sovereignty and tikanga about data in the clinical trials system. • Ensure knowledge translation has a positive impact for Māori and reduces inequities in health outcomes. • When funding mechanisms are developed, ensure they are responsive to Māori community needs and researcher obligations. • Support and train tauiwi workforce to engage with Te Ao Māori. • Active development and support for the Pacific health research workforce. • All publicly funded clinical trials should include consumer research partners. • There should be a national federated health data system with Māori data governance at the core that allows the embedding of research in routine clinical care and provides culturally appropriate long-term curation of research data. • A clear responsibility for research knowledge translation and implementation must be established within Aotearoa New Zealand's new healthcare system that is well integrated with change management, clinical governance functions, and the health system's role and responsibilities as an effective Te Tiriti partner for Māori.

Figure 1: Proposed structure.

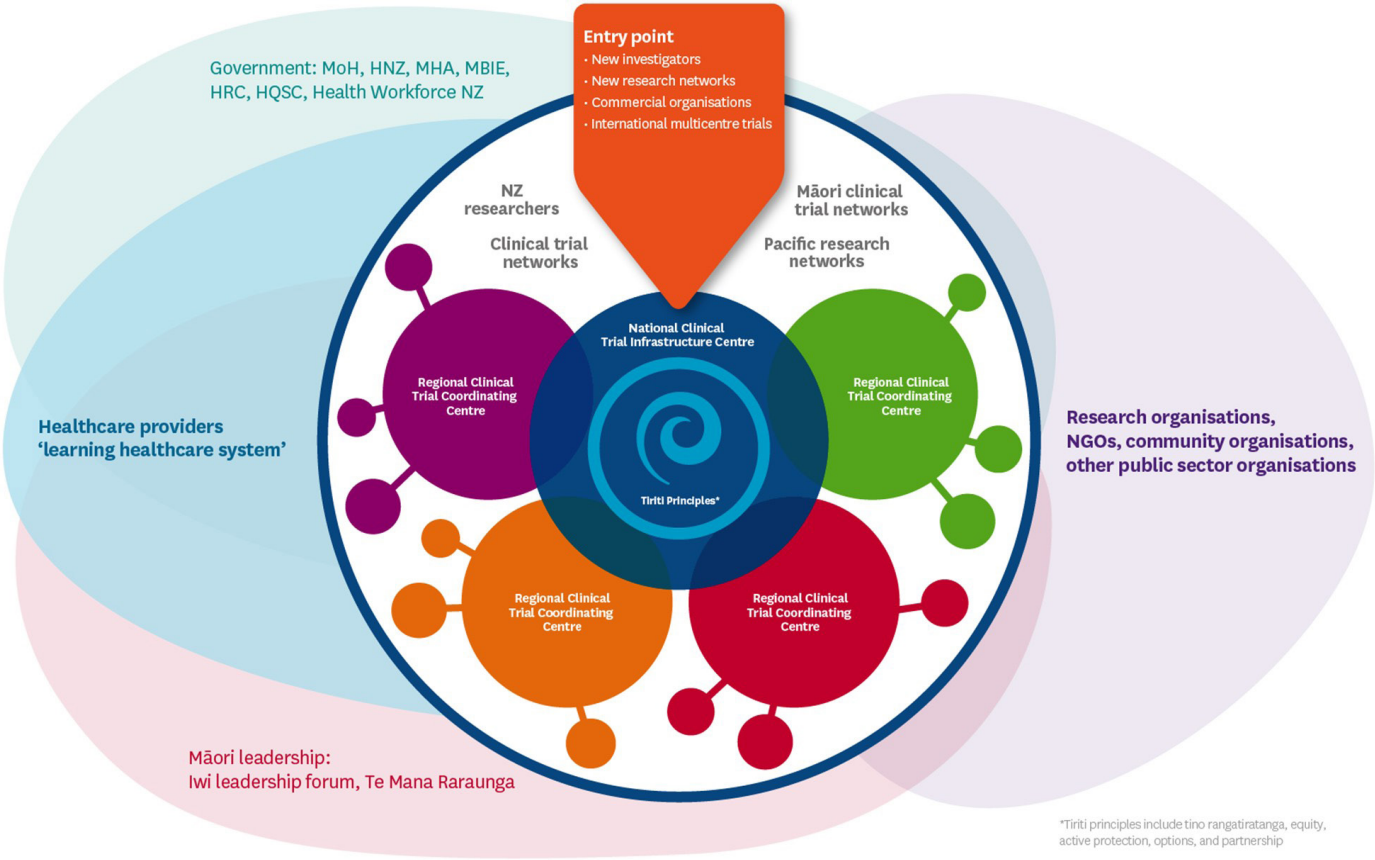


Table 3: Legend for the diagram of the proposed model.

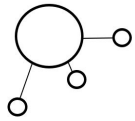
Legend	Description of component
	**National Clinical Trial Infrastructure Centre** (section 6.3.1) *Collaboration of expertise and key stakeholders from across the country to provide leadership and national support for clinical trial activity*: • Governance and advice • Administration and data systems • Signpost, information collation, connections, and marketing • Education and methodology.
	**Regional Clinical Trial Coordinating Centre(s)** (section 6.3.2) *Region-specific collaborations between academia, healthcare providers, Kaupapa Māori services, Iwi Māori Partnership Boards, and other research organisations to support the development and conduct of investigator-led trials using a system of regional nodes*: • Partnership and engagement • Prioritisation of local research need and resource use • Expertise and support.
	**Entry point** *New researchers, new research networks, commercial organisations, and international trials will access the infrastructure through the National Clinical Trials Organisation*.
Government	*The leadership of the national clinical trials infrastructure should include representation from government departments and agencies to ensure research is embedded and resourced*: • Manatū Hauora – Ministry of Health • Te Whatu Ora – Health New Zealand • Te Aka Whai Ora – Māori Health Authority • Ministry of Business, Innovation and Employment • Health Research Council of New Zealand • Health Quality & Safety Commission • Health Workforce New Zealand.
Healthcare providers "learning healthcare system"	*Functional relationships between the clinical trials infrastructure and healthcare providers are essential for embedding research in healthcare and moving towards a learning healthcare system*.
Māori leadership	*Māori leadership would be embedded within the national clinical trials infrastructure; functional relationships with national Māori organisations, including the Iwi Leadership Forum and Te Mana Raraunga, are also critical*.
Allied organisations	*The leadership of the national clinical trials infrastructure should include representation from research organisations (including universities), NGOs, community organisations such as consumer groups, and other relevant public sector organisations*.

Table 4: Proposed timeline.

Action	Month 0	3	6	9	12	15	18	21	24
Assign key leadership roles to develop implementation plan, co-governance	◆								
Development of implementation plan by responsible government agencies	■	■							
Funding/mandate at government-level for clinical trials infrastructure		■	■						
Appoint central research support team & establish co-governance structure			◆						
National organisation operational with initial high-level function			■	■	■				
Further define roles needed within supporting organisations and interactions with central			■	■	■				
Expression of interest (EOI) for support organisations					◆				
Work with organisations submitting EOIs, where possible promote joint ventures					■	■	■	■	■
Formation of clinical trial coordinating centres						■	■	■	■
Clinical trial coordinating centres operational and Māori and Pacific networks established									◆

Consumers have important and rapidly growing roles in clinical trials and in making sure research is relevant and meaningful. Through the consultation process we have heard there is a need to create more opportunities for consumers to be research partners at all stages of the clinical trials process.

There is relatively little focus on translation of research results into practice. Translation is a particular issue for Māori given the extractive nature of research, the need to tailor results for Māori providers, and a need to demonstrate positive benefits for Māori to participate in trials. From the healthcare system perspective, translation is important to ensure the knowledge obtained from clinical trials improves clinical practice.

Thus, it is clear that any new infrastructure established must provide an opportunity for partnership with Māori, embed Te Tiriti o Waitangi, and allow for Māori to have greater leadership and governance to ensure Māori responsiveness (see full analysis at https://cdn.auckland.ac.nz/assets/liggins/docs/Appendix%20A-M%c4%81ori%20Relevant%20Themes%20in%20the%20Enhancing%20Clinical%20Trials%20Project.pdf).

Proposed infrastructure

The proposed essential elements of the infrastructure are outlined in Tables 2, 3 and Figure 1. Our proposal consists of two main components: 1) a National Clinical Trial Infrastructure Centre that provides and manages some of the functions and activities that have been agreed to be critical through the Delphi survey process (such as the website, facilitation of access to resource, coordination of key stakeholder groups such as consumers, Rōpū Māori and Pacific Advisory Group), and 2) a number of Regional Clinical Trial Coordinating Centres, procured by the National Clinical Trial Infrastructure Centre, that provide and manage operational functions and activities either at local level, across specific communities or more widely where there is specific expertise, on behalf of the Infrastructure Centre. Supporting organisations may be consortia or could contract other organisations as suppliers for necessary resources. Further details can be found in the full report (https://cdn.auckland.ac.nz/assets/liggins/docs/HP8537%20-%20LIG_Clinical%20Trials_FINAL_v6.pdf).
Importantly, such an infrastructure will benefit all health research, not just clinical trials being undertaken within the public healthcare system.

Table 3 explains the components of the diagram of the proposed model.

Why now?

In April 2021, the Minister of Health announced a restructuring of the Aotearoa New Zealand health system, consolidating the 20 district health boards into Te Whatu Ora – Health New Zealand and Te Aka Whai Ora – Māori Health Authority, which will both operate hospital services and commission primary and community healthcare. This national approach provides the ideal opportunity to integrate and embed research into Aotearoa New Zealand's healthcare system.

We recognise that the integration of clinical trials and research more broadly into the public healthcare system will require a significant shift in the culture within our healthcare system. The significant structural changes underway with Te Whatu Ora – Health New Zealand and Te Aka Whai Ora – Māori Health Authority mean that now is the ideal time to enact such change. The required cultural change will need to be led from the top down with appropriate key performance indicators with respect to research for managers. Research must be recognised and promoted as a core activity for clinical staff at all levels of the healthcare system, rather than something to be tolerated or even hindered.

Kaupapa Māori health research is a vital mechanism for Māori to gain tino rangatiratanga (self-determination) within research and maintain control and autonomy over the knowledge considered relevant and legitimate to Māori.[3] Kaupapa Māori research, in the broadest sense, embeds the principles of being Māori and Te Ao Māori worldview within research by acknowledging the "Māori way of doing things".[4] To realise the currently unmet potential benefits of clinical trials, and particularly to ensure equity of access to participation in and realisation of the benefits from clinical trials will require both the system culture change and considerable building of capacity and capability in the Māori, and also Pacific, health research workforce.

Investment required

The investment required by the Government to implement the proposed clinical trial infrastructure will be substantial. In the first instance, at least 10 years' funding will be required in order to see a complete clinical trial cycle from

study design to funding, trial completion and reporting. It is therefore vital that the decision makers understand the financial benefits to the healthcare system of clinical trials. A study of the spill-over effects of public investment in health research in the UK found that every additional £1 GBP of public spend was associated with an eventual additional £0.99 GBP of private research and development spend in the UK.[5] Combined with other estimates of rate of return on investment, the findings suggested investment into public medical research in the UK retrieves a return between 15 and 18% per annum. This return was also thought to potentially be additive to other estimates, extending the estimated rate of return to a conservative 25% per annum.[6,7] Studies looking at the return on Australian health research and development investment produced benefit-cost ratio (BCR) estimates between 2.2:1 and 5:1.[8–10] This means that, at the time, for every $1 AUD of costs, there were between $2.17 and $5 AUD of benefits. A further study focusing only on the Australian National Health and Medical Research Council (NHMRC) expenditure estimated a BCR ratio of 3.2:1 from $10 billion AUD of R&D funding, highlighting benefits of (in AUD): $7.7 billion reduction in burden of disease, $1.3 billion direct health system expenditure savings, $1.9 billion reduction in productivity loss, $0.6 billion reduction in other financial costs, $0.3 billion reduction in deadweight loss, and $2.6 billion value of commercialisation.[11] A scoping review of 288 clinical trials concluded there are spill-over benefits for healthcare systems, including better health outcomes, enhanced research capacity, and drug cost avoidance.[12] Thus, the value of investing in clinical trials is net positive for funders through improved health outcomes, cost avoidance, and spill-over effects that encourage wider private spending. It is in health providers'/funders' best interests to ensure and support clinical trial activity. A proposed timeline for implementation is seen in Table 4. There exists substantial expertise in clinical trials across the Aotearoa New Zealand health system, and we note the importance of preserving and enhancing this in the development of the national clinical trials infrastructure.

We recognise that we are in a time of significant financial pressure within the health system and more generally within the economy. However, as noted above, there are financial savings to a public healthcare system engaged in research. Furthermore, it is critical that the development of clinical trials and other research infrastructure is considered and coordinated as part of the reorganisation of the health system at community, primary, and secondary levels. For example, coordination of the development of research infrastructure with the development of national health data systems is essential for enabling the embedding of research in clinical care and progress towards a learning healthcare system. In this regard, it is pleasing to see that Te Whatu Ora – Health New Zealand has appointed a Director of Evidence, Research and Clinical Trials, who will be responsible for the oversight of developing a plan to implement the Enhancing Aotearoa New Zealand Clinical Trials recommendations in collaboration with Manatū Hauora – Ministry of Health and Te Aka Whai Ora – Māori Health Authority, as well as providing strategic direction and leadership over embedding research as a priority within Te Whatu Ora – Health New Zealand.[13]

Summary

Now is the ideal time for investment in clinical trials infrastructure in Aotearoa New Zealand. Engagement with a broad range and large number of stakeholders demonstrated enormous enthusiasm and broad consensus for the approach outlined herein. Strong leadership will be required to ensure the required cultural shift to recognise the value of clinical trials to all aspects of the healthcare system, and to grow the capability and capacity of the health research workforce. We urge the Government to be bold and invest now to ensure the benefits can be reaped for all New Zealanders in years to come.

COMPETING INTERESTS

Lisa K Stamp, Matire Harwood, Stuart Dalziel, Katrina Sharples, and Frank Bloomfield are active clinical triallists. Funding from Health Research Council of New Zealand and the Ministry of Health.

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REFERENCES

1. Reid IR, Joyce P, Fraser J, Crampton P. Government funding of health research in New Zealand. N Z Med J. 2014 Feb 14;127(1389):25-30.
2. Joyce P, Reid IR. Health research funding: international comparisons with New Zealand. N Z

Med J. 2008 Sep;121(1208):7.
3. Mikahere-Hall A. Constructing research from an indigenous Kaupapa Māori perspective: An example of decolonising research. Psychother Politics Int. 2017 Oct;15(2):e1428. doi: 10.1002/ppi.1428.
4. Curtis E. Indigenous Positioning in Health Research: The importance of Kaupapa Māori theory-informed practice. AlterNative: An International Journal of Indigenous Peoples. 2016 Dec;12(4):396-410. doi: 10.20507/AlterNative.2016.12.4.5
5. Sussex J, Feng Y, Mestre-Ferrandiz J, Pistollato M, Hafner M, Burridge P, et al. Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom. BMC Med. 2016 Feb 24;14:32. doi: 10.1186/s12916-016-0564-z.
6. Grant J, Buxton MJ. Economic returns to medical research funding. BMJ Open. 2018 Sep 10;8(9):e022131. doi: 10.1136/bmjopen-2018-022131.
7. Health Economics Research Group, Office of Health Economics, RAND Europe [Internet]. Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK. London: UK Evaluation Forum; 2008 Nov [cited 2022 Aug 12]. Available from: https://www.ukri.org/wp-content/uploads/2022/02/MRC-030222-medical-research-whats-it-worth.pdf.
8. Access Economics [Internet]. Exceptional Returns: The value of Investing in Health R&D in Australia. Australia: Australian Society for Medical Research; 2003 Sep [cited 2022 Aug 12]. Available from: https://asmr.org.au/wp-content/uploads/library/Except.pdf.
9. Access Economics [Internet]. Exceptional Returns: The value of Investing in Health R&D in Australia II. Australia: Australian Society for Medical Research; 2008 Jun [cited 2022 Aug 12]. Available from: https://asmr.org.au/wp-content/uploads/library/ExceptII08.pdf.
10. Latera Economics [Internet]. The Economic Value of Australia's Investment in Health and Medical Research: Reinforcing the Evidence for Exceptional Returns. Australia: Research Australia; 2010 Oct [cited 2022 Aug 12]. Available from: https://lateraleconomics.com.au/wp-content/uploads/2014/02/The-Ec-Value-of-Austs-Invmt-in-Med-Research.pdf.
11. Deloitte Access Economics [Internet]. Extrapolated returns from investment in medical research future fund (MRFF). Australia: Australian Society for Medical Research; 2014 Oct [cited 2022 Aug 12]. Available from: https://asmr.org.au/wp-content/uploads/library/ASMR%20Deloittee%20Report_MRFF.pdf.
12. Bentley C, Cressman S, van der Hoek K, Arts K, Dancey J, Peacock S. Conducting clinical trials-costs, impacts, and the value of clinical trials networks: A scoping review. Clin Trials. 2019 Apr;16(2):183-93. doi: 10.1177/1740774518820060.
13. Te Whatu Ora – Health New Zealand [Internet]. Service Improvement and Innovation Consultation Document. Wellington: Te Whatu Ora – Health New Zealand; 2023 Mar [cited 2022 Aug 12]. Available from: https://www.nzdoctor.co.nz/sites/default/files/2023-04/Consultation%20Pack%20-%20Service%20Improvement%20and%20Innovation%20consultation%20document.pdf.