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.

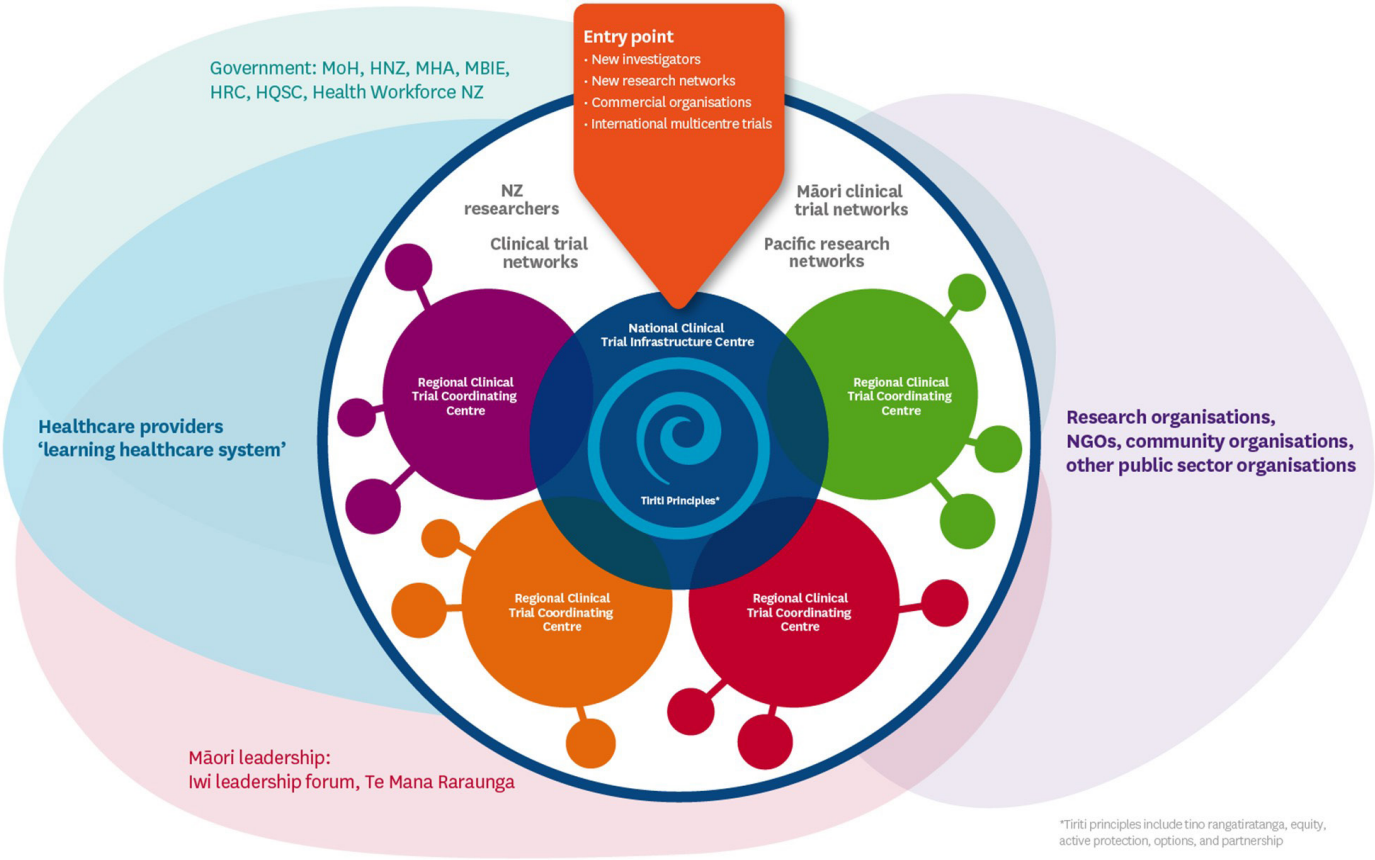


Table 3: Legend for the diagram of the proposed model.

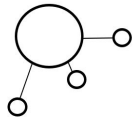
Legend	Description of component
	**National Clinical Trial Infrastructure Centre** (section 6.3.1) *Collaboration of expertise and key stakeholders from across the country to provide leadership and national support for clinical trial activity*: • Governance and advice • Administration and data systems • 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	