Appendix G Key principles and mapping of activities to the model

Where activities/functions should be managed by the National Clinical Trial Infrastructure Centre

In a perfect world, resources (and funding) would not be scarce, and health would be able to be funded alongside other areas of society, rather than in competition. New Zealand is a comparatively small country with relatively low health funding and a small population, meaning unfortunately, decisions made to fund health typically have great trade-offs in other areas of society.

Where possible and appropriate, controlling some of the aspects of clinical trials infrastructure nationally will allow for gains in efficiency and minimisation of operation costs. This will ensure the most amount of funding is available for the activities that matter and help to deliver better, more equitable health outcomes – clinical trials.

Below highlights some of the justification principles for where activities might be best held at a central, national level.

Economies of scale

Economies of scale refers to the cost advantages gained by an organisation by doing something at a large scale (or in large quantities) (Stigler, 1958). The cost advantages are gained because at a large scale (or in large quantities) an organisation can become much more efficient (and/or specialised) at what they do.

It therefore makes sense to conduct activities relating to the clinical trial infrastructure at a central, national level when there are likely to be economies of scale from doing so. For example, providing trial randomisation services at a central, national level may exhibit economies of scale and allow for efficiency gains through automation compared to if supporting organisations all had to have their own randomisation service.

Large transaction costs

Certain activities such as contracting, procurement, networking management, and facilitation all have associated transaction costs that arise from having to link with other organisations and follow certain procedures. In complex systems with a lot of relationships to manage (like the health and disability sector which has lots of constituents), the associated transaction costs of activities can become large and ultimately create a significant financial burden on an organisation.

Organisational theory of transaction costs dictates that organisations form when the organisations can arrange transactions between their different parts and relationships at a lower cost than available in the open market where all parts are separated (Williamson, 1981). Therefore, activities where transaction costs are likely to be high (such as contracting, procurement, networking management, and facilitation) may benefit from being managed centrally and nationally to limit transaction costs.

Benefits of standardisation and cohesion

Standardisation and cohesion in this sense refers to having well-defined and coordinated approaches for certain activities that also have buy-in from those performing the activities. The benefits of standardisation and cohesion come mainly through reductions in operation costs through increased efficiency and interoperability.

The main examples where there are benefits of standardisation and cohesion are in the data domain and applying standardised frameworks for capture, analysis and management, and sharing of data. Standardisation of data capture, analysis and management tools, and ways sharing of data will result in efficiency gains by reducing the time burden associated with cleaning, preparing, and transforming data for different purposes and to go to different places. Literature has shown the benefits of health data interoperability to be substantial (Walker et al., 2005).

Strong link of accountability

Activities such as upholding standards, updating and disseminating clinical best practice, and reviewing the operation of the system (guardian-type role) may be best suited to be included at a central, national level. Responsibilities for these activities sitting with too many separate organisations blurs the link of accountability and could result in outcomes that are less than ideal.

No clear link of accountability for certain activities within the system may cause organisations who are responsible to shirk, pass blame elsewhere, and not uphold their obligations to the system. Having the activities mentioned above managed centrally and nationally may resolve these issues by ensuring the link of accountability is clear. All other activities will still require clear links of accountability and "owners" within the system, however this may be at different levels.

The link of accountability works the other way as well. Having these functions at a central, national level allows for consumers, Māori, Pacific, and other research partner groups within the organisation to hold the management of the system accountable as well and ensure different population groups are reflected and well captured by the system.

Where activities would be better managed by the Regional Clinical Trial Coordinating Centres

There are numerous activities that do not make sense to be managed or conducted by the National Clinical Trial Infrastructure Centre. These would make more sense to be managed or conducted by the Regional Clinical Trial Coordinating Centres.

Activities that cannot (and should not) be done remotely and are not automated

Most operational level tasks that cannot be done remotely and are not automated should be done at a lower-than-national level by one of the Regional Clinical Trial Coordinating Centres. For example, managing datasets for specific trials may be better suited to be run by a Regional Clinical Trial Coordinating Centre that is geographically and figuratively close to the trial, rather than the National Clinical Trial Infrastructure Centre because:

- there may be greater ability to communicate about the project in a timely and effective manner

- the data manager will be able to immerse themselves in the context of the trial and therefore act on it much more efficiently
- there are likely benefits of the data manager being near the primary investigator as well as statistical support to ensure cohesive approach to data capture, management, and analysis.

Where links into communities are required

Regional Clinical Trial Coordinating Centres would be best placed to manage activities that link trial activity and the health and disability system to communities. This is because the National Clinical Trial Infrastructure Centre would never be able to effectively manage and tailor their approach to community engagement for each individual community and population sub-group. A generalist approach to community management would neglect the variation we see across the country and likely reinforce inequities in access to, and benefits from, clinical trials.

Regional Clinical Trial Coordinating Centres would be better placed to deal with geographical variation in populations, population needs, support mechanisms and infrastructure, and culture based on their own geographical position. Being at a lower-than-national level provides the discretion to tailor the Regional Clinical Trial Coordinating Centre's approach for a much more specified area of people. As such, the approach to tendering a Regional Clinical Trial Coordinating Centre for these activities would likely need to be permissive and allow for adjustment in approach based on the context and the population, needs, and support systems and infrastructure.

For example, a Regional Clinical Trial Coordinating Centre in Northland would be able to focus their activities on the characteristics of the region, as would a Regional Clinical Trial Coordinating Centre in Southland. Both organisations, however, would likely have significantly different approaches in response to different population make-ups, needs, and local support systems and infrastructure. The National Clinical Trial Infrastructure Centre in this case would struggle to be able to deal with both separately.

Having localised links with iwi and Māori health partners is also extremely important and should be managed by Regional Clinical Trial Coordinating Centres. Kanohi ki te kanohi, or face-to-face engagement is described as a key principle of being and doing as Māori (Ngata, 2017). Therefore, there must be resource situated outside of a national setting (i.e. outside of the National Clinical Trial Infrastructure Centre) to allow for this where possible.

Below shows the activities/functions mapped to the project workstreams, and where we believe they should be managed. There are some instances where it makes sense for activities/functions to be managed at both levels.

Workstream	Activity/function	Activity/function should be managed by National Clinical Trial Infrastructure Centre	Activity/function should be managed by Regional Clinical Trial Coordinating Centre(s)
Clinical trial activity, infrastructure, and networks	Strategies for Māori health advancement	Yes	
	Governance and advice on Māori data sovereignty	Yes	
	Governance and advice on developing relationships with iwi, Pacific, consumers for co-design and partnership	Yes	
	Governance and advice on funding availability	Yes	
	Coordinated information resource on trial activity in NZ	Yes	
	Governance and advice on data governance, systems, curation, and sharing	Yes	
	Advice on adverse event recording and reporting	Yes	
	Advice regarding handling, storage, and disposal of human specimens	Yes	
	Accountability for education of public about benefits of CTs to NZ and to individuals and their whānau who participate in CTs	Yes	
	National guidelines for determining which trials are supported by organisations that support the infrastructure	Yes	

	Advice on research methods for working with Pacific communities	Yes	
	Data Safety Monitoring Committee set-up and advice	Yes	
	Advice on trial methodology, including design of complex or innovative trials and statistical expertise	Yes	
	Advice on health economics	Yes	
	Governance and advice on national approach to locality assessment	Yes	
	Advice on trial pharmacy services	Yes	
	Availability of infrastructure to industry through funded model / entrance point for industry	Yes	
	Monitoring and audit activity	Yes	
	Consumer engagement, including recognised patient groups		Yes
	Support with Māori community engagement and Māori health advancement		Yes
	Development of protocols, data management plans and other trial documentation		Yes
	Statistical input into the design, conduct, and analysis of trials		Yes
	Ethics and regulatory approval		Yes
	Site locality approval		Yes

	Health economics input into the design and analysis of trials, where health economics needs to be considered		Yes
	Support for finance and budgeting		Yes
	Database design, provision, and maintenance		Yes
	Innovative data capture including text messaging, data from wearable devices and innovative data entry		Yes
	24-hour randomisation service, including randomisation, unblinding, and drug delivery		Yes
	Access to accredited pharmacy services		Yes
	CT management system (software to manage all aspects of clinical trials, including progress and reporting)		Yes
	National coordinated approach to data governance, that recognises indigenous data sovereignty	Yes	
	Federated repository for long-term storage of data collected in CTs	Yes	
	Management of availability of data collected from publicly funded NZ-led trials for other New Zealand researchers	Yes	
Collaboration	National resource of people and information to support CT activity	Yes	
	Resource underpinned by set of values that promote a culture of collaboration	Yes	
	Resource has publicly accessible register of actively recruiting CTs	Yes	

	Provision of opportunities between consumers, Māori, Pacific and researchers to meet	Yes	Yes
	Database of trial expertise for potential collaboration	Yes	
	Governance body to develop and implement funding models that promote/support collaboration	Yes	
	Database of key stakeholders for collaboration	Yes (provide)	Yes (access and refer people to)
	Provision of collaboration opportunities such as virtual meetings or workshops	Yes (perhaps in an awareness role, but not hosting them)	Yes (more hosting of them)
Knowledge translation, implementation, and prioritisation	Clinical trial activity occurring to identify areas of specific importance for local communities, including Māori		Yes
	Priority setting (considering and including potential health gain, feasibility of research, feasibility of implementation of intervention, ability to achieve health equity, consumer engagement, wider societal gain, community engagement, whether population to be researched is typically under-researched)	Yes	Yes (by discipline-based networks also)
Consumers	System for identifying diverse range of consumer-research partners (Māori, Pacific, rural, disabled, youth, collectives)	Yes	
	System for supporting and empowering consumer-research partners	Yes	
	System for educating and supporting researchers in engaging with consumer-research partners	Yes (managing and oversight)	Yes (operational)
	Support for consumer-research partner networks	Yes	

	Inclusion of consumer-research partners		Yes (not sure this line totally fits in this assessment framework)
	Remuneration system for consumer-research partners roles in CTs (outside of participation)	Yes	Yes
Networks	National CT alliance that provides forum for networks to share ideas, best practice, resource	Yes	
	Access to administrative support for networks	Yes	
	Transparent process for reviewing, at appropriate intervals, which networks should receive support from infrastructure	Yes	
	Knowledge translation and implementation		Yes (individual researchers' responsibilities within supporting organisations to promote frontier knowledge)
	Providing lay summaries of results from CTs	Yes (on national CT centre site)	
	Provision of support to disseminate CT trial results to Māori, Pacific, rural, and other key stakeholders	Yes	
	Systematic review and NZ-specific guideline development	Yes	
Workforce development	Training and accreditation in Good Clinical Practice (GCP) that is free for all	Yes	
	Provision of GCP programme that has been tailored for NZ	Yes	
	Modular training programme that upskills users in CT methods	Yes	

	Ensuring job security and career pathways for people in CT workforce	Yes	
	Other training programmes available to all, although some may come at a cost	Yes	
	Establishment of CT research career pathways for investigators	Yes	
	Recognition of CT research activity as core part of being a HNZ employee	Yes (strategy setting)	Yes (operational level)
	Embedded research roles in community to support CT activity across system, including iwi and Māori health providers	Yes (strategy setting)	Yes (operational level)
	Managing costs of embedded research roles		