

## Appendix F Delphi survey results

Below are the final results of the Delphi survey. The survey consisted of three survey rounds, each lasting 21 days, followed by a consensus meeting.

The consensus meeting objective was to confirm the options from round 3 that reach consensus for inclusion or exclusion and discuss and finalise a decision on the options that did not reach a consensus. Selected members from the Investigator Reference Group, Māori Advisory rōpū, Pacific Advisory Group and Consumer Focus Group who participated in the Delphi were invited to participate in the Consensus Meeting. This was done to ensure a broad representation in the session and that one group was not overly or under-represented.

The group reviewed and voted on the options for inclusion/exclusion based on the **infrastructure components** that were deemed **critical** to 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. During the session, some of the options were voted on based on changes to the wording. These are noted in the option lists below.

The following fundamental principles underscore the options:

- reducing inequity
- increasing access and participation
- implementing options relevant to Aotearoa New Zealand.

We heard through consultation that there is a need throughout Aotearoa New Zealand to better support clinical trials. It has been suggested that the required infrastructure should have a role in governance, as well as providing practical assistance in undertaking individual clinical trials.

The proposed solution is a national clinical trials body to provide:

1. Governance and advice at a **national level** (national clinical trial centre) and
2. Support to clinical trial hubs at a **regional level** (regional hubs).

## Clinical Trial Design and Coordination

### National Level Options

**Option question:** How do you rate the importance of the following governance and advice activities being provided at a national level?

#### Options meeting the voting criterion for inclusion as critical

- At a national level, governance and advice on strategies to support Māori health advancement through clinical trials
- At a national level, governance and advice on Māori data sovereignty
- At a national level, governance and advice on developing relationships with iwi, Pacific, consumers for co-design and partnership

- At a national level, governance and advice on funding availability e.g., registry of all clinical trial funding available
- At a national level, a coordinated information resource on trial activity e.g., consumer-facing registry of all clinical trial activity
  - Adjusted wording from “governance and advice” to “a coordinated information resource”
  - Original wording: “At a national level, governance and advice on trial activity e.g., consumer-facing registry of all clinical trial activity”
- At a national level, governance and advice on data governance, systems, curation and sharing
- At a national level, advice on adverse event recording and reporting
- At a national level, advice regarding handling, storage, and disposal of human specimens
  - Added “disposal of human specimens” to option
  - Original wording: “At a national level, advice regarding handling and storage of human specimens”
- At a national level, accountability on education of the public about the benefits of clinical trials to Aotearoa and to individuals and their whānau who participate in clinical trials
  - Adjusted wording from “governance and advice” to “accountability”
  - Consensus group voted on the basis that there is a national level responsibility around developing the awareness of clinical trials to the health care sector and the people who take part
  - Original wording: “At a national level, governance and advice on education of the public about the benefits of clinical trials to Aotearoa and to individuals and their whānau who participate in clinical trials”
- At a national level Transparent national guidelines for determining which trials are supported by the clinical trials hubs
- At a national level, advice on research methods for working with Pacific communities
  - Adjusted wording from “governance” and changed “Pacific research methods” to “research methods for working with Pacific communities”
  - Original wording: “At a national level, governance and advice on Pacific research methods”
- At a national level, Data Safety Monitoring Committee (DSMC) set-up and advice
- At a national level, advice on trial methodology, including design of complex or innovative trials and statistical expertise
  - Removed “governance”
  - Original wording: “At a national level, governance and advice on trial methodology, including design of complex or innovative trials and statistical expertise”
- At a national level, advice on health economics
  - Removed “governance”
  - Original wording: “At a national level, governance and advice on health economics”
- At a national level, governance and advice on national approach to locality assessment
- At a national level, advice on trial pharmacy services
- National clinical trials infrastructure being available to industry through an appropriately funded model
- The following advice being provided at a national level trial: monitoring and audit activity
  - Removed “governance”
  - Original wording: “The following governance and advice being provided at a national level: trial monitoring and audit activity”

### Option *not* meeting the voting criterion for inclusion as critical:

- At a national level, governance and advice on national approach to site identification

### Regional/Local Level Options

**Option question:** How do you rate the importance of the following activities being supported at a regional/local level?

### Options meeting the voting criterion for inclusion as critical:

- Supported at a regional/local level: Consumer engagement, including recognised patient groups
  - Added “including recognised patient groups”
  - Original wording: “Supported at a regional/local level: Consumer engagement”
- Supported at a regional/local level: Support with Māori community engagement and Māori health advancement
- Supported at a regional/local level: Development of protocols, data management plans and other trial documentation
- Supported at a regional/local level: Statistical input into the design, conduct and analysis of trials
  - Consensus group voted on the general idea that it will be available for researchers in all regions of NZ but may not necessarily physically be in all regions.
- Supported at a regional/local level: Ethics and regulatory approval
- Supported at a regional/local level: Site locality approval
- Supported at a regional/local level: Health economics input into the design and analysis of trials, where Health Economics needs to be considered
  - Added “where Health Economics needs to be considered”
  - Original wording: “Supported at a regional/local level: Health economics input into the design and analysis of trials”
- Supported at a regional/local level: Finance and budgeting
- Supported at a regional/local level: Database design, provision, and maintenance
- Supported at a regional/local level: Innovative data capture including text messaging, data from wearable devices and innovative data entry
- Supported at a regional/local level: 24-hour randomisation service, including randomisation, unblinding and drug delivery
  - Added “including randomisation, unblinding and drug delivery”
  - Consensus group voted on the ability to do randomisation, unblinding and drug delivery
  - Original wording: “Supported at a regional/local level: 24-hour randomisation service”
- Supported at a regional/local level: Access to accredited pharmacy services
- Supported at a regional/local level: Clinical trials management system (software to manage all aspects of clinical trials, including progress and reporting)

## Data governance and long-term curation

Data governance refers to the processes for ensuring integrity, security, and the appropriate usage of data. This includes the provision of a data 'Safe Haven', a system for data curation which has the highest standards of security, with reliable systems for controlling where data sits, and who has access to the data both during the trial and into the future.

While many people have indicated they have systems in place for data curation, others found this more challenging.

Requirements around Māori Data Sovereignty are being addressed separately by the Māori rōpū.

**Option Question:** How do you rate the importance of the following for ensuring appropriate data governance and usage of Aotearoa New Zealand trial data?

### Options meeting the voting criterion for inclusion as critical:

- A national, coordinated approach to data governance, which recognises indigenous data sovereignty
- Aotearoa New Zealand to have its own national federated repository for long term storage of data collected in clinical trials
  - Adjusted wording from "national repository" to "national federated repository"
  - Original wording: "Aotearoa New Zealand to have its own national repository for long term storage of data collected in clinical trials"
- Once a trial is finished, data collected from publicly funded New Zealand-led trials should be available to other researchers in New Zealand for approved purposes

### Option *not* meeting the voting criterion for inclusion as critical

- Once a trial is finished, data collected from publicly funded New Zealand-led trials should be available to other researchers overseas for approved purposes, subject to data sovereignty, privacy and IP concerns being met
  - Added "subject to data sovereignty, privacy and IP concerns being met"
  - Original wording: "Once a trial is finished, data collected from publicly funded New Zealand-led trials should be available to other researchers overseas for approved purposes"

## Collaboration

We heard through consultation that collaboration is important in undertaking successful clinical trials, but many felt that it was piecemeal and uncoordinated. In addition, the current funding models do not foster collaboration.

**Option question:** How do you rate the importance of the following to support and foster collaboration across Aotearoa New Zealand?

### **Option meeting the voting criterion for inclusion as critical:**

- A national resource of people and information to support clinical trial activity
- The resource is underpinned by a set of values that promote a culture of collaboration
- The resource has a publicly accessible register of actively recruiting clinical trials
- The resource provides opportunities for meetings between consumers, Māori, Pacific, and researchers
- The resource provides a database of trial expertise for potential collaboration
- A national governance body to develop and implement funding models that promote/support collaboration
- The resource provides a database of key stakeholders for collaboration
- The resource provides 'collaboration' opportunities such as virtual meetings or workshops

### **Options *not* meeting the voting criterion for inclusion as critical**

- The resource has a password-only access register of actively recruiting clinical trials
- The resource provides 'collaboration' opportunities such as in-person meetings or workshops

## **Prioritisation**

Resources are limited, whether that be allocation of funding, dedication of staff time and infrastructure, or capacity of the health system to recruit participants. Thus, there is a need to prioritise clinical trial activity to addressing areas of importance to New Zealander's and our health system, representing best possible investment of the limited resource.

Through our consultation we have heard that prioritisation is not consistently undertaken for clinical trial activity.

**Option question:** How do you rate the importance of the following aspects of prioritisation of clinical trial activity?

### **Options meeting the voting criterion for inclusion as critical:**

- Clinical trial activity should occur at a regional/local level to identify areas of specific importance for local communities including Māori
- Clinical trial prioritisation should consider potential health gain (impact) of the research
- Clinical trial prioritisation should consider feasibility of the research
- Clinical trial prioritisation should consider feasibility of the implementation of the intervention
- Clinical trial prioritisation should consider the ability to achieve health equity across all Aotearoa New Zealand and its peoples including Māori, Pacific and rural
- Clinical trial prioritisation should include consumer engagement
- Clinical trial prioritisation should consider wider societal gain (impact) of the research
- Prioritisation should be undertaken by discipline-based clinical trial networks
- Clinical trial prioritisation should include community engagement
- Clinical trial prioritisation should consider if the population to be researched is an under-researched population

## Options *not* meeting the voting criterion for inclusion as critical

- Clinical trial prioritisation should consider the potential to increase capacity equitably within Aotearoa New Zealand's clinical trial workforce
- Clinical trial activity should occur at a national level to identify areas of specific importance to Aotearoa New Zealand
- Prioritisation is the responsibility of funders (e.g., Health Research Council, Charitable organisations)
- National prioritisation should be undertaken by the proposed national clinical trial centre
- Regional/local prioritisation should be undertaken by the proposed regional hubs
- Clinical trial prioritisation should consider the potential cost-effectiveness of the intervention
  - Adjusted wording from "consider cost-effectiveness" to "consider the potential cost-effectiveness"
  - Original wording: "Clinical trial prioritisation should consider cost-effectiveness of the intervention"
- Clinical trial prioritisation should consider the potential for scientific advance/novelty of the intervention

## Consumers

Health consumers have a rapidly growing role in clinical trials. Partnering consumers with researchers throughout the clinical trial process ensures questions that matter to consumers are addressed, and that the experience of the trial participants and the value of the results is optimised.

Through the consultation process we have heard that there is a need to create more opportunities for consumers to be research partners. Consumers find the culture around clinical trials and the lack of training opportunities impact on their ability to make a meaningful contribution.

**Option question:** How do you rate the importance of the following for ensuring consumer engagement in clinical trials?

## Options meeting the voting criterion for inclusion as critical:

- Aotearoa New Zealand should have a national system for identifying a diverse range of consumer-research partners (Māori, Pacific, rural, disabled, youth, collectives)
- Aotearoa New Zealand should have a national system for supporting and empowering consumer-research partners
  - Adjusted wording from "national system for educating and training consumer-research partners" to "national system for supporting and empowering consumer-research partners"
  - Original wording: "Aotearoa New Zealand should have a national system for educating and training consumer-research partners"
- Aotearoa New Zealand should have a national system for supporting and educating researchers in engaging with consumers-research partners
  - Adjusted wording from "educating researchers" to "supporting and educating researchers"
  - Original wording: "Aotearoa New Zealand should have a national system for educating researchers in engaging with consumers-research partners"

- Aotearoa New Zealand should support consumer-research partner networks
- All publicly funded clinical trials should include consumer-research partners
- Consumer-research partners should be offered remuneration for their roles in clinical trials (this is not remuneration for participation as a participant in a clinical trial)
  - Adjusted wording from “Consumer-research partners should be remunerated” to “Consumer-research partners should be offered remuneration”
  - Original wording: “Consumer-research partners should be remunerated for their roles in clinical trials (this is not remuneration for participation as a participant in a clinical trial)”

## Networks

Clinical Trials Networks are often based around disciplines or disciplinary areas. We have heard through the consultation process that clinical trials networks across Aotearoa New Zealand are vulnerable but are essential for effective running of multi-centre clinical trials.

Specific infrastructure to support Māori and Pacific networks are being addressed separately by the Māori rōpū and Pacific Advisory Group respectively.

**Option question:** How do you rate the importance of the following in supporting the effective functioning of clinical trial networks in Aotearoa New Zealand?

### Options meeting the voting criterion for inclusion as critical:

- A national clinical trials alliance that provides a forum for the networks to share ideas, best practice, resource
- Access to administrative support for networks
- A transparent process for reviewing, at appropriate intervals, which networks should receive support from a national clinical trials infrastructure

### Options *not* meeting the voting criterion for inclusion as critical

- An access point / navigator role for international multi-centre public good trials seeking sites in Aotearoa New Zealand
- Information on clinical trial activity across Aotearoa to identify capacity for involvement or lack thereof
- An access point / navigator role for industry seeking sites to participate in industry-sponsored clinical trials

## Knowledge Translation

Knowledge translation, the action of getting evidence into clinical practice, is critical to ensuring continuous improvement in the health care system and that patients receive the highest quality care.

Through consultation, we heard that knowledge translation is variable, and that there is a lack of national support and emphasis in this activity.

**Option question:** How do you rate the importance of the following for knowledge translation and implementation of clinical trial findings?

### Options meeting the voting criterion for inclusion as critical:

- Health New Zealand/Māori Health Authority/Ministry of Health, supported by the Health and Quality Safety Commission, should be responsible for ensuring effective knowledge translation and implementation to achieve equity across Aotearoa New Zealand's health system
- A lay summary of the results from clinical trials should be posted on the Aotearoa New Zealand national clinical trial centre site
- The proposed clinical trial infrastructure should provide support to disseminate clinical trial results to Māori, Pacific, rural and other key stakeholders
- A dedicated national infrastructure to fund systematic review and Aotearoa New Zealand-specific guideline development
- Individual researchers or networks should be responsible for ensuring effective knowledge translation and implementation to achieve equity across Aotearoa New Zealand's health system

### Options *not* meeting the voting criterion for inclusion as critical

- The proposed national clinical trial centre should be responsible for ensuring effective knowledge translation and implementation to achieve equity across Aotearoa New Zealand's health system
  - Consensus Group noted that the proposed national clinical trial centre may have a role in/share responsibility rather than being responsible
- The proposed regional hubs should be responsible for ensuring effective knowledge translation and implementation to achieve equity across Aotearoa New Zealand's health system
  - Consensus Group noted that the proposed regional hubs may have a role in/share responsibility rather than being responsible

## Workforce Development

A sustainable workforce is critical to the long-term success of clinical trials in Aotearoa New Zealand.

Through consultation, we have heard that the workforce is vulnerable, and research is not seen as an attractive career due to financial instability and lack of a defined career pathway.

There are major issues with regard to recruitment and retention into the workforce particularly with respect Māori and this is being dealt with separately by our Māori rōpū.

### Workforce: National Options

**Option question:** How do you rate the importance of the responsibility for the following being provided nationally?

### Options meeting the voting criterion for inclusion as critical:

- Being provided nationally: Training and accreditation in Good Clinical Practice (GCP)
- Being provided nationally: A GCP programme that is has been tailored for Aotearoa New Zealand



- Being provided nationally: GCP training and accreditation that is free for all
- Being provided nationally: A modular training programme that upskills users in clinical trials methods
- Being provided nationally: Job security and career pathways for people in the clinical trials workforce
- Being provided nationally: Other than GCP, other training programmes should be accessible to all, although some may come at a cost
  - Adjusted wording from “Other than GCP, training programmes should be accessible to all on a user-pays basis” to “other training programmes should be accessible to all, although some may come at a cost”
  - Original wording: “Being provided nationally: Other than GCP, training programmes should be accessible to all on a user-pays basis”
- Being provided nationally: Established clinical trials research career pathways for investigators

### **Option *not* meeting the voting criterion for inclusion as critical**

- Being provided nationally: Training and accreditation for other licences that may be required to undertake certain types of clinical trials e.g., Principle Investigator licences as defined in the new therapeutics bill

## **Workforce: Sustainability Related Options**

**Option question:** How do you rate the importance of the following in achieving a sustainable clinical trials ecosystem across the whole of Aotearoa New Zealand?

### **Options meeting the voting criterion for inclusion as critical**

- For District Health Board staff, clinical research activity should be recognised as an integral part of the job
- Research roles should be embedded within hospitals to support clinical trial activity
  - Adjusted wording from “Research coordinators and research nurses” to “Research roles” to be more inclusive
  - Original wording: “Research coordinators and research nurses should be embedded within hospitals to support clinical trial activity”
- Research roles should be embedded in the community to support clinical trial activity across the healthcare system, including iwi and Māori health providers
  - Added “including iwi and Māori health providers”
  - Original wording: “Research roles should be embedded in the community to support clinical trial activity across the healthcare system”
- Costs of embedded research roles should be underwritten by Health New Zealand

### **Options *not* meeting the voting criterion for inclusion as critical**

- Providing physical space at a local level to accommodate research activity
- Costs of embedded research roles should be subsidised by trials utilisin