

Appendix C Interview analysis

Commercial trial activity

Stakeholder views about clinical trial activity are summarised below:

- commercial trial activity is seen as a useful addition by stakeholders
- benefits are access to new medicines and, for some, a surplus to invest in public good research
- some happens in public settings, but the private network is important
- NZ has a good reputation for being quick off the mark and for recruitment
- But other countries are doing it well are competing at a national and state level
- There is limited capacity in New Zealand and funding rules around compassionate supply, and tougher decisions around subsidisation, mean some pharmaceutical companies won't trial here
- MedTech demand is increasing and is not well served and, being start up activity, needs clinical trial sites at a reasonable cost.

There was a generally positive view about undertaking commercial clinical trial activity, nicely summarised by one stakeholder who noted the benefits to recruitment, of access to medicines and spill-over effects, being money.

Commercial clinical trials are seen by many investigators as a useful addendum to New Zealand's health sector. Many clinicians are seeing clinical trials as a way of giving access to new medicines for their patients. The opportunity to participate in these trials is seen as important to senior medical officer recruitment. A few stakeholders noted that there was some spill-over from commercial clinical trials but the main spill-over appeared to be money. Indeed, commercial clinical trials come with money, generally, it would seem, about \$10,000 per patient, and this funding is keenly sought by some.

Just now, New Zealand's ability to contain COVID-19 has had a positive impact.

Getting more trials coming back to NZ now than for a long time (COVID).

Competing for commercial trials

Pharma trials sit in their own competitive environment. Pharmaceutical companies weigh up which country and site to use based on a range of requirements – the right patient group, speed to recruit and ability to retain patients, quality of the clinical trial site and cost. Speed to market is particularly important for pharmaceutical companies in the biotech market. Some factors work for New Zealand and some against. The quality of clinical trial sites was generally considered to be good.

In the past had haemophilia unit in trials, were conducted in NZ (trial sites in NZ). They recruited and performed particularly well; has no qualms about performance of trial sites in NZ, high quality, high standard trial sites generally.

Pharmaceutical company stakeholders noted that it was a hard sell to establish trials in a small, remote economy, from the perspective of their head offices.

Recruitment and patient numbers

All stakeholders who commented on the subject noted that New Zealand had good recruitment and retention rates.

Looking at ANZCTR completed commercial trials and those that report both target and actual sample size, NZ and Australia are at 103% recruitment. Internationally this is something to be proud of.

Really well meaning that the recruitment is good and stacks up against other countries, and SMOs are dedicated, and the systems work for them (use of private and public based sites, taken from DHBs and moved to private hospitals).

However, for some drugs, several stakeholders noted that we have a very limited patient pool and that may mean that we are not appropriate as a site for some trials.

Numbers of patients is important.

In the sponsor world they are starting to use some of the competitive edge in NZ. Couple of things about recruitment - If we can't get the recruitment numbers, we can't get the sponsorships to do those studies. For example, because of smaller population, unless it's a type of trial where the patients are organised and ready to go, then you have a longer recruitment period. Other countries that have bigger populations that can recruit faster take it. Must be quite strategic about trial placement at a site.

There is some but not much oncology [clinical trial activity] ...I thought it would be a need, but we are competing against Royal Marsden in the United Kingdom etc and might need 20 people with a type of lung cancer so can't get the participants. So, recruitment of participants an issue.

Patient numbers also feed into market potential and ability of pharmaceutical companies to quickly recoup any research costs through sales.

Recruitment – some of the areas we have traditionally (15 to 20 years back) been able to do had decent sized numbers in P3 trials, especially the likes of respiratory, there are lots of people with asthma in New Zealand. We are not seeing that now, not necessarily getting the same trials. The clinical trial attractiveness is now determined by market potential if the medicines are likely to be used in New Zealand.

The regulatory environment and ability to move quickly

The regulatory environment is seen as particularly important and needs to be supportive of commercial clinical trial activity. Stakeholders noted the importance of being fleet of foot in approving trials through Scott and ethic approval mechanisms. Nor does New Zealand impose rules for instance around the numbers of New Zealand patients that need to be recruited.

New Zealand is seen as competitive in seeking part of the clinical trials market as it is quick through the ethical and other regulatory hurdles and recruitment and retention are good.

NZ doesn't have requirements for submission of data as a sponsor. Doesn't have to have amount of NZ patients. In US companies have to have so many x [number of] US patients

or equivalents. In Korea, have to have x [number of] Koreans in the P3 to register the drug there. Some countries have the requirements to be able to allow the drugs in. NZ is seen as equivalent with the US based on performance. China has certain requirements in what is submitted to them, Taiwan as well. When going to P3 have to look at that.NZ accepts anything.

Some stakeholders note the advantage needs to be maintained and not whittled away by requirements in New Zealand, at the same time as Australia streamlines its regulatory processes.

NZ ethics and timelines are giving advantage now, but Australia are catching up and removing our advantages.

Ethics in NZ has fortnightly loop, in Australia it takes longer to get to the Central Ethics Committee and easier to miss (extends the timeline). Also has a layered process, NZ has one process. Australia is getting better and different states are starting to accept each other's ethics applications so they can be strategic about it. The data has flipped on us and it is becoming a lot easier to be done in Australia. Need to figure out the root cause of this. [....] has the data and it has slowed right down and flipped; contracts could be an issue. Pre-COVID reasonings for it? 150 plus days for all documents and submission, hard to tease out where the effect is.

Ethics committee are hugely under resourced and need more focus from the ministers to be able to do the applications. Diversity of committees is causing huge delays. There are too many studies to run post-COVID. It is a huge burden for the heads of the committees – controlling two regions each and getting underpaid for their work. There is not enough capacity to do it all.

When ethics submissions go to site level there is need to understand more than the requirements – there might be a training gap which could be causing the slow down.

Start-up time frames used to be fast and ethics and reg used to be ok. There are now delays with ethics and regs – slowing down of that in NZ which potentially may be to do with some of the delays with ethics now. Fully transparent, but likely have resourcing issues at the ethics approval.

One stakeholder emphasised that every clinical trial manager wants to be fast through the trial both for the company and also for the patient. This was this pharmaceutical company's perspective.

Don't do a lot of trials in New Zealand, and have two trials now, one is a P4 study, other one is P1 – P3 in [condition]. The reason for the P1 – P3 is just historical and circumstantial, people travelled overseas for the study. Once it was over, there was long-term extension into NZ for it for people to fly to Australia from NZ, but COVID happened and then they were stuck. P1 centring in Christchurch was excellent in getting the trial up and running and patients back into treatment. This is an ideal example of New Zealand being able to move quite quickly in terms of study start up. It is working better than in Australia. Australia is trying to achieve faster timelines but is stuck at governance contract negotiations. This is where New Zealand is seen as having an advantage.

Other countries are getting into the game

We would appear to have an enduring advantage when compared with the United States as the process of approval is much slower. Australia is both a direct competitor and an opportunity to collaborate. Other countries are entering the market.

Now in a situation where we have different regions, Australia and NZ are now competing in the [drug company] world for clinical trials. There is Chinese and Brazilian competition. This will make life interesting

On the United States:

The lack of speed in the United States is seen as a competitive advantage. The lack of needing an USIND to commence trials in NZ and Australia means quicker speed of recruitment and start up. There are a number of different stages to go through in the States to do a clinical trial which slows everything down. There is an investigation on drug approval from FDA. In non-scientific terms, this means getting the old Testament of the bible – including a full on [investigation of] pre-clinical data to demonstrate that it is fit for purpose for humans. This is a very complex and very expensive process

Our advantage over Australia is diminishing:

Australia doing a lot of things right; from a competitive situation, they are the neighbour we need to compete with or collaborate more with. A 43.5 per cent research and development grant is available for global sponsors in Australia. To be cost competitive with Australia, we must do something. The New South Wales state government is looking at a lot of initiatives aligning across hospitals and is really taking research seriously. Governance models, having teleTrials are coming into some of the trials across sites. This means they can provide more oversight and have treatments at people's current locations.

On Asia:

One of the biggest threats is that the emerging Asian market is becoming strong. ... We need to take the Asian market threat seriously, more who can deliver trials rapidly, much bigger populations, and starting to get the infrastructure they didn't have around clinical research. ... We must be careful about hanging on to what we had and were good at and need to be aware of the environment changes around us that might only really be coming up now.

Therapeutic excellence has been important

Some of this is also about clinical excellence in some therapeutic areas.

NZ strong on certain types of therapeutic areas and can perform well. What we do, we do really well. Dedicated clinicians and investigators who give a lot of their own personal time to research, despite the full clinical loads. They prioritise research over that. Despite some of the barriers, we have people that override that and deliver Non-oncology really stands out, oncology is almost like a different conversation entirely. RINZ respiratory do exceptional studies, cardiology as well do well. Gastro, hepatitis, etc.

There is a lack of research depth which may play against New Zealand

The disadvantages of New Zealand are that we don't have Phase 1 clinical trial groups and some stakeholders indicate the Phase 2 clinical trials tend to follow. Also, New Zealand competes with well-established clinical trial centres such as Melbourne, those in the United Kingdom. Those trial centres have strong institutional linkages with their health system, size and capability, all strong indicators of a productive science system. However, it is not clear to others that Phase 1 means Phase 2 on will follow.

My concern is the growth in Australia is an awful lot off the Phase 1 units. In comparison, NZ doesn't have as much. There is more growth in the opportunities for P1 – the rest follow generally (P2, P3, P4). New Zealand is well behind the Australian growth for these, and we need more sites and more focus around the attraction for global trials here. We have good data, good outcomes etc.

New Zealand for some time has had flat growth; the number of trials is constant over time, as opposed to the higher amount for Australia. It looked like the mix of trials was swinging more from later phase to earlier phase in NZ, but it is too early to comment entirely. Phase 1 research tends to be carried out in the private sector, not really a big thing for the DHBs. A couple of DHBs that have unit space for Phase 1s, but must compete with their clinical trials, with DHB work and normal clinical care.

Must be careful to push more P1; a lot of places are pushing for it (Taiwan, Korea), not something sponsors go for in a lot of cases. Very relationship based and isolated to some specific units. I don't know if it is a huge area to scope in with later phases as well, for a sponsor it doesn't necessarily work that P1 leads through to later phases as well. Proportionately we are about right but opening one in every major NZ city is going to grow the industry significantly. The swing to earlier phases distracts from the risk going toward conducting the later phase ones productively and effectively.

The role of international experts

The role of international experts was debated. For many, they saw that these international experts were able to build and support clinical trial units, but then may disappear as the expert retires. For instance, one stakeholder referenced a research group reducing from 13 to two staff on retirement of the expert. Others were more positive, noting that the advantage comes from the ability to offer clinical trial capacity rather than having the expert. There is no doubt, however, that most worry that New Zealand's current advantage may fade in some therapeutic areas with the retirement of some New Zealand based, internationally recognised experts.

At the moment have some internationally recognised key opinion leaders for CTs in some areas, where any sponsor desires to work with them because they are well regarded. The difficulty is they are ageing and will want to retire. Not clear who wants to fill their space. The thing with these people is that they can reach out across medical communities and get primary practitioners and other clinicians referring to them etc. which helps their ability to recruit immensely.

Staying competitive

There was comment but one knowledgeable stakeholder that New Zealand needs to keep up with international medicines regulatory initiatives, to allow it to stay competitive.

You may not be aware of going forward is the ACCESS consortium of sharing regulatory information and resources and fast track registrations. There are shared regulatory functions. This regulatory initiative is starting to look at moving into the clinical trial area for looking at ethics approvals etc. The consortium will cover 150 million people and includes Australia, Canada, the United Kingdom and Switzerland. New Zealand declined to be part of that. I don't know why Medsafe declined being part of that. We will have to go through the process for NZ when we go through Australia which will be a big issue in ten years. We are isolating ourselves. This will not be a problem for about five years, but we need to look long-term.

Trial capacity is limited

Pharmaceutical companies were concerned that New Zealand's capacity to run the trials is limited and one pharmaceutical company identified that it had around 30 opportunities, but it was likely to be able to place only ten. The companies emphasised the difficult for them of advocating for clinical trials in a small remote economy and therefore the importance of being agile and cost-effective.

There are several, small clinical trials groups, several of which have been acquired by Australian private equity. A few of these small groups operate private wards space for trials.

The general feeling amongst stakeholders is that public capacity is limited by a mix of competing demands on senior doctors and, also, some philosophical differences.

There must be some drivers for Principal Investigators and in the DHB environment it doesn't see many people putting their hands up for this. They are too conflicted. Wellington oncology aren't accepting any trials for six to nine months, Canterbury DHB is not accepting them. They claim resource constraints – that they don't have people to step in and help them. We cannot upskill people and don't have the access or money to put in this. It means that only Auckland is left.

The time and resources in the DHB model is the issue. There is strain across DHBs and the trained individuals who support the doctors are not present.

There are a lot more oncologists in Wellington than the three (sic) that will do research – a lot are refusing to do it.

The private network is important

Private clinical trial infrastructure is seen as a great help. It is seen as flexible, responsive and assists with building clinical trial capability and capacity. Recently, there has been private equity into New Zealand private clinical trial centres suggesting an expansion of capacity particularly for biotech companies.

Private can remove some of the study barriers. Some studies have to be in DHB sites and a lot of extra time delays and approvals then have to be incurred. Some doctors know where the trials should be held.

Within private network, some of the more experience PIs can take on training of new investigators, would give the industry a lot more opportunity than what is being seen.

Pharmaceutical companies are positive about the private network and would like to see it expand.

We are very positive about private sites. We don't have that many of them. They are very engaged, very quick to respond. We are really counting on them. They [the smaller trial centres] are up and coming. would be lovely to see a private site in Wellington, in Dunedin.

Collaboration with DHBs is important

There were several suggestions for improving capacity in the public sector. The main gain seen by stakeholders would come through increased collaboration. Then, patients could jump from one DHB to another, rather than having to come to one centre. There could be some ability to match across DHB database, that would improve the ability to recruit. The information systems could be improved so that data was coded rather than scanned off a PDF (e.g., Waikato DHB's records are on paper).

DHBs don't have the physical space, resources, and the support services around the researchers to do their own research. Some flat out refuse to do any commercial research. We find that the Middlemore model works well, feeding the wider research in New Zealand from the profits from commercial research. Only Auckland DHB has an attached set up like this. It is a good model, drives more research, means dedicated focus and research professionals who can leverage DHB connections and infrastructure, removes some of the resource constraints, know their own staffing ability etc.

DHB referrals as well – cannot refer an oncology patient from one DHB to another so there is a barrier, even though they might have a rare form of cancer or something specifically useful.

DHB borders are an issue that hopefully will be resolved in the new Health NZ.

One stakeholder saw collaboration as particularly important in future.

When you introduce NZ sites, there is a unique collaborative opportunity in NZ – it is more institutionalised and siloed in Australia at sites.

Pricing is important

New Zealand has been reasonably priced but views on that are now changing. The source of the cost increases appears to be from DHB costs and laboratory costs. There is concern by stakeholders about overhead charges and how they are used. Overhead charges are appropriate but the clinical trial sponsors need to see that the overhead charges are reinvested in support for the clinical trials.

Our clinical research unit is across Australia and New Zealand...it is now cheaper to do work in Australia but used to be [cheaper] in New Zealand. I think DHBs are seeing it as a profit making.

Pricing of some sites has gone up considerably which doesn't help the market. Problem across the board, but Middlemore are a bit more difficult to negotiate with because of their private funding experiences.

[Stakeholder thinks] some DHBs take quite a big clip of the trial ticket in terms of the overhead for the research offices. I am not sure this money goes back into the funding for the trials.

Some investigators for ADHB are getting funds and then fighting with research office to actually be able to do the hands-on part of the research and get the funding to be able to staff their trials. It is not very motivating to do trials when you aren't able to do them at capacity desired. At a system level can push the fees back into that direct department.

Smoke and mirrors perhaps – commercially overheads could be up to 30%. What are they doing for that proportion? There is no one questioning whether the overheads are correct?

There is a charge in Australia as well, but we actually see the use of the overhead in their studies and the support around it.

When you are looking at a sponsor, why go to New Zealand if you then have to provide the additional support and the additional infrastructure. May disincentivise studies from coming to NZ as a single site (i.e., might want to put the rest of them in Australia where the support already is).

The funding environment has an impact

Many years ago, sponsorship of clinical trials came with public funding of pharmaceuticals, usually block buster drugs in the cardiovascular, asthma or mental health arenas. However, as Pharmac got started, and rules around compassionate supply were introduced, the money for drug trials, particularly marketing trials, dried up.

Plenty of money around and sponsorship driven by pharma that gave good grounds and experience initially.

Sponsorship dried up dramatically with revamp of PHARMAC and the rest in late 90s. Being involved and source of clinical trials was harder.

New Zealand is generally seen to be a follower in subsidisation of pharmaceuticals, and this is both a good and bad influence. Some stakeholders noted that they some pharmaceutical companies may not bring trials here as the companies did not think their pharmaceuticals would ever be funded. In immunology, one stakeholder noted it is advantageous to have a treatment naïve population.

[Pharmaceutical company] has an issue with providing ongoing therapy for patients, or those with chronic therapies. New Zealand is typically twelve months behind Australia in terms of regulatory approval. If a trial finishes, then there is a long moral obligation for [supply of the pharmaceutical to] patients. Setting up continued supply is an expensive business for the affiliate, and it comes down to [the Australian subsidiary] having to set it up. It is as expensive for one patient as it is for 50 patients, as you have to have some level of importation, distribution, a whole lot of stuff. Unpredictable [nature of] (in some sense) of funding in medicines in NZ drives that further. In Australia, we got a level of confidence that treatments will be reimbursed. PHARMAC instils little confidence. The obligation to patients is seen as ongoing with no real end.

Most companies are not there to support NZs health system.

Cancer trials are becoming difficult and contentious, for several reasons. In New Zealand, subsidisation of new cancer treatments is a can of worms, as FDA rules changed to allow earlier phase approval based on surrogate endpoints, or on evidence from non-randomised trials. Thus, clinical trials become part of the marketing phase of a pharmaceutical, and there are more and more molecules passing this reduced threshold. New Zealand's ability to compete for clinical trials is faltering at times as the standard of care expected in the trial design assumes pharmaceuticals that are not subsidised in New Zealand.

In adult cancer, however, clinicians noted that the control arm of a cancer drug trial may assume a standard of care different to that offered in New Zealand, because of growing gaps in New Zealand's funding of cancer drugs. Almost all of these trials are big pharma trials, and they focus in on immunology and cancer, with one diabetes drug trial being mentioned.

When the FDA changed rules around cancer drugs, it opened a can of worms. It is coming to a point where conducting trial in NZ is hard. It assumes we have access to some cancer agents which we just do not have funded.

Quite a few first-line treatments not available in NZ; therefore, cannot do the trials where we are comparing new treatments.

A major problem is PHARMAC. The drugs aren't funded in this country and so are cut out of some exciting and important questions and advances in care. One instance it was supportive and that is the only time it was for a \$650 drug for a patient so not really expensive. Was within the budget of the DHBs. It was a logical approach and the PHARMAC person was logical.

We still don't have drugs funded here that were in the United Kingdom five years ago. This is getting worse not better; we can't access standard of care drugs. New Zealand is falling so far behind other countries that there will be no research soon.

[Researcher name] lost four studies in New Zealand because of lack of standard of care for oncology. We are getting so far behind that there are no patients available. Then it becomes a question of whether it is worth funding standard of care, i.e. in lung cancer, we just haven't kept up with the rest of the world and are not [researching] in that area anymore. No immunotherapy is funded for lung cancer patients, so have chemo; in the rest of the world it is registered but not funded. We don't have the people who failed immunotherapy because they are all doing chemo, so the populations aren't prepared for it. We cannot place the second- or third-line studies here in NZ.

May not be quite as obvious, but probably an issue in some of the rare disorder conditions as well. Even in some of the bigger health conditions as well there would be issues with SOC not being kept up with, and not keeping up with international best practice for clinical care.

Seen as a way of accessing drugs for patients

Researchers indicated that commercial trials are also seen as a way of accessing pharmaceuticals, particularly expensive pharmaceuticals, for patients.

Commercial trials give a good drop in the ocean in terms of funding and also access to drugs for patients which improve outcomes, regardless of their funding types.

The biotech industry is also experiencing a sharp rise in activity driven by this regulatory change and also by the Orphan Drug Act in the United States. There are a substantial number of biological agents in the pharmaceutical pipeline all looking for places to trial, but there is a question of placement of New Zealand in this pipeline, due to subsidisation issues and issues of scale.

[Drug name] clinical trial in NZ shouldn't be viewed as research; it is an avenue to get drugs for people. It is a step in the therapeutic process.

Cross-subsidising public good activity

Gaps in sustainable public funding is filled by researchers who might undertake commercial trials.

[Name of researcher] has a dedicated research group generating funds from pharma trials. The idea is that the money is cross specialised to allow for cooperative group trials in the TT oncology group. This is the way that most clinicians want to do a trial; keep all the data, make sure it is publishable, and in things they are interested in. Non-pharma trials is why he is interested. They are the ones they want the answers to, funding is the main problem for this.

The surplus generated off trial revenue is used by DHBs and some other research organisations to help out with public good trials. Sometimes this is about using any surplus from clinical trials to fund or top-up public good trials, sometimes it is about helping to sustain the research teams that might also undertake public good activity, and sometimes it is a philanthropic gesture by a clinical trial organisation to offer infrastructure to colleagues undertaking public good research.

Commercial trial activity that is usually pretty well funded leaves surplus often for studies and is often held for non-funded or poorly funded research areas. There is likely \$10 million sitting there in the active pool, generates a bit of income and that is made available for competitive grant provisions within the organisation. Our DHB is probably using a bit more sophisticated financial system than most DHBs and research offices. The surplus stays with the department and they can apply to use it. They can use it for their studies, but it is not available to use without application. This is a \$500-600,000 a year investment earnings to be used for research, which is helpful for giving funding to people starting out etc. The criteria for access are normally equity, scientific merit particularly advancement of emerging researchers and research – and there is a role to encourage new research.

Christchurch tackled things in a different way, and we have used revenue from commercial studies, and it has been a life saver. There are a small number of pharmaceutical trials and the clinician initiated are the more important cutting-edge ones. They can be long term studies e.g., AL study Is nine years not including follow up. Our data shows 70/30 investigator initiated, the same as in Australia. We use commercial.

Medical devices industry in New Zealand is still largely emerging

The issues for the medical devices sector are quite different. New Zealand's medical device companies, other than a few exceptions such as Fisher & Paykel Healthcare, and ARANZ Medical, are start-ups. These start-ups have difficulty gaining access to senior medical officers and to DHB's and their patients even to the extent that it is easier for them to create opportunities overseas.

This area of work has become quite diverse in New Zealand and includes apps, medical software such as Silhouette for wound care, respirators, etc.

Seeing a lot more medtech studies coming through now, really increased in the last year or two.

Need is huge for the biotech companies, a huge number of requests. We have created our own market and people come to [research unit] first before universities now. We can only take a small proportion of the approaches because of resource constraints. We could be doing ten times the size right now because of the COVID boom, but don't have the resource.

The stakeholders identified the needs of this industry sector:

- One point of access to DHBs
- Clinical buy-out of time
- Ability to translate success to other DHBs

Clinical trials have not been needed for medical devices in the past although, sensibly, most are certified clinically in some way. However, regulatory requirements are changing particularly in the European Union and, eventually, we will see more clinical trials with medical devices. These clinical trial mechanisms can be problematic.

By the time we get something to a clinical trial, we have done everything we can do in-house. Choose to do clinical trials and pre-market release testing to get it honed. We go in circles with ethics committees, hospital review boards.

For example, we had a new Continuous Positive Airway Pressure interface trialling. It got completely snarled for almost nine months. It was the internal hospital research review committee that held it up. We weren't sure of their concerns, and still aren't clear. We think they may have been looking for a more comprehensive investigator brochure looking at risks and safety. We had the information, but not packaged for the review because we weren't aware it was a process we had to go through.

One well established medical device supplier noted the positives of the current arrangement, for them and their business. There is a close partnership with clinicians that has matured over the years, resulting in innovation that is then commercialised, and expanding in scope. The development process is usually incremental, such as trialling a new face mask or pipe, and less suited to application of a clinical trial perspective, something that ethics committees can have difficulty with.

We have a long-term relationship with Middlemore to solve various clinical problems extending into neonatal care. This is often where the most vulnerable patients are and the most technical challenges. It works well from an innovation point of view.

Case study – a commercial/ clinical partnership in medical devices

Experience we have had over the years, worked on both sides of interaction – hospital and commercial. When you get really motivated, invested clinicians working together with engineers to solve clinical problems, we can come up with great ideas that have the potential to change care for millions of patients globally. We have done this with multiple innovations at [company name]. got a fantastic relationship with a number of critical care physicians where we have been able to repeat the experience on a number of cases and increasingly broadened the different clinical applications, moving from respiratory through to surgery, neonatal etc. We have been able to replicate this partnership really well across the different sections.

We spent a lot of time working with a way of delivering oxygen therapy to patients with a high-flow nasal thing. We developed it in the Middlemore intensive care unit and did some of the early clinical trials on these products at two units (including Middlemore). We have gone from people in disbelief [and have now] demonstrated that it worked really well. It is now being used to treat millions of patients, especially with the COVID response. It has been growing, but even more now. We have been watching that evolve over the last 15 years from wacky idea of blowing humidified gas up someone’s nose until getting to frontline response has been rewarding.

We are thinking about expanding portfolio because of our good relationships and brand. Often clinicians coming to us with ideas, as opposed to us having to approach them.

The environment is difficult for start-ups

The environment for start-ups is more difficult and goes beyond that of clinical trials. Universities are seen as expensive particularly with the loading for salaries. Start-ups find it hard to get DHBs to work with the – there is no “one-front-door”. DHBs promise things but clinicians are overruled by others. There is the need for buy-out of clinician time. Timeliness is critical to a start-up. It is hard to find reference sites and generally New Zealand companies have looked overseas after not finding a reference site in New Zealand.

For a start-up, if I can’t get what I need and work with a DHB, I’d rather know sooner or later. Time is of the essence.

Equity in clinical trials

Note: does not include analysis from Māori interviews conducted by Māori interviewers

It is apparent that equity is not at the forefront of the clinical trials system and lacks appropriate consideration through the design, conduct, and dissemination of trials.

Māori and Pacific advancement, in general, is not well done

Māori health advancement is not being done well from a national point of view (e.g. only six Māori paediatricians out of 220 and one nephrologist and none are Pacific. Only two Māori or Pacific in Emergency Medicine).

Equity is not well understood, and people lack guidance and resources

A main issue identified is that equity is not well understood, especially regarding outcomes, treatments, and access to clinical trials. For some researchers, they feel there is no mechanism for ensuring equitable design, access, treatment, and outcomes for different population groups.

In a specific example we heard researchers are generally ill-equipped to incorporate Pacific populations into the design, conduct, and dissemination of trials.

Don't have a mechanism for it and don't understand it fully, a real issue for them.

Pacific peoples not traditionally included or even thought of to participate in trials that might have a lot of impact for them (i.e. diabetes). The researchers, majority non-Pacific, do not get the messages out to the Pacific communities, or do not know how, to get their involvement. Once you explain a trial to the Pacific community, they see the relevance of participating in a trial and the relevance of contributing to the greater good. With that comes the caveat that they always want to know the result – will you tell us whether the medication will be useful? Important that they can see the results tangibly. Explained well, benefits portrayed, information dissemination good to ensure participation.

When looking wider than just Pacific, interviewees stated that consumer input was sometimes low in the designing and conduct of trials which can create a mismatch between research outputs and actual consumer health needs.

We have no consumer input, they don't attend but on a larger scale some groups will have consumers groups.

Other interviewees made it apparent that prioritisation does not exist in a systematic way when considering equity in clinical trials design, access, treatments, and outcomes. This may leave traditionally underserved populations such as Māori and Pacific worse off and without focus on their issues as European and Western lenses are applied in a generalised way to health research.

We don't have a prioritisation approach to New Zealand outcomes. No health-related quality of life tool for Māori and Pacific. So we can't do the work that is key for them. We use a European quality of life tool. There are also health utility tools and we don't have one of these either this is important for health economics. May be some coming out of the University of Otago for Māori but haven't seen it yet.

The workforce struggles with equity and is overburdened

Consensus shows there is a clear lack of workforce capability to promote equity in trial design, conduct, treatments, and outcomes and people would like there to be more formal training and support mechanisms.

There needs to be workforce development [regarding equitable trials].

From a funder perspective need to be investing in support for building capability in research by and for Māori and Pacific peoples.

Areas where people are nervous about, and don't know much about. Need training and exposure for the young clinicians coming through to feel more comfortable with it.

Takes time to build—most Māori organisations that have capacity or capability will be approached constantly. Has to facilitate aspirations for themselves.

Some interviewees expressed concern that Māori co-workers and researchers are being loaded with responsibilities for engaging with Māori communities and whānau simply because they are Māori, despite not necessarily having the training, capability, or capacity to do so.

Don't want Māori co-workers to be loaded with these responsibilities just because they're Māori.

Number of people to do this research is so small (by Māori, for Māori).

Not enough to just be Māori: Not resourced with people who are skilled at responding to such questions. Post-doc said they don't think they're trained to do that, despite being Māori. They also said they weren't employed to do that. Hospitals Māori unit may be prepared to take it on, but with some reluctance.

Areas where people are nervous about, and don't know much about. Need training and exposure for the young clinicians coming through to feel more comfortable with it.

Lack of engagement of Māori and Pacific in all aspects of clinical trials that stems from lack of understanding of equity

Interviewees highlighted concern over the level of engagement of Māori and Pacific in clinical trials. Even in areas of high need and disease prevalence for these populations (such as gout, diabetes, etc.) there is little effective engagement or recruitment.

Don't think we get equity in engagement and Māori participation in research trials. Prevalence is 3 times and we recruit to the population distribution. Should reflect the populations we treat not the DHBs we serve. Very few studies do that. It is a challenge.

Māori underrepresented in the trial, unsure why that is in the sampling for their trial (10,000 people in the Auckland area). Getting about 8–9% Māori patient recruitment. Sees this as decent explanatory power for the Māori population. Cautious about what they frame as questions.

Huge populations available for Māori and Pacific, but haven't had a lot of engagement and ways to engage.

Hard to recruit but also to keep them in a trial as they are a highly mobile and transient population, and they will want to hide if feel they fail (e.g. if smoking restarts or same with alcohol and diet or physical activity).

Even when effort is made, it can still be difficult to recruit due to a range of limitations such as locality and the type of research being conducted.

Try actively to recruit where possible, but Māori are a small percentage of population in Dunedin which can make it hard for the recruitment.

[Engagement] easier said than done, depending on what work you are doing. Work done is not always a priority for Māori health, especially if you have to tick the problems off a list. Not top of everyone's mind that it is a problem (although it is).

Haven't run a lot of trials with Māori, however because of the older population I work with.

It was also suggested that access to participation is not well considered and groups that are often underrepresented may have too much going on in their lives to be able to effectively engage with the trial.

May be issues with equity with those that are needed or need it most may not be able to do so because of overcommitment etc.

Further, interviewees reiterated that participation and access take on a Westernised/European-centric lens that may make it hard for Māori and Pacific to engage with the trial or discourage involvement.

Equity in participation not well connected to Māori world. Need Māori workforce development in DHBs. How do we do this better we need leadership, maybe from central government.

Problem not the engagement with Māori, it is more about engagement mechanisms.

Pacific is just another step behind Māori – even behind the ideas and ontologies.

Huge disconnect between clinical trials researchers and Pacific communities. Do not engage them. Biggest thing is that we don't have enough Pacific researchers, that would understand and engage with the Pacific community.

Interviewees told us that there have been minor advancements made in the equity space but believe there is still a long way to go to embed equity in trials.

[Must] ask applications for impact and translation – [currently] funding a lot of very basic biomedical research though, so varies. Have in mind though—redeveloped the post-doc funding roles, new considerations for them regarding equity focus.

Post-doc is now getting more of an inequity focus, haven't really done it much with the others. Once this is on board, will be doing within the other applications as well, even in doc scholarship level. Largely a work in progress

Terrible stats consistently over history for Pacific peoples (e.g. of child births etc.). Without the leadership, we don't know how to learn from these and put this into practice. People (especially MoH) do not put in interventions.

Location plays a big part in inequity of access to clinical trials for both researchers and patients

A significant issue is around equity of access to clinical trials because of location. There is a distinct lack of infrastructure in some areas/regions that means people effectively play a 'post code lottery' and must be in the right place at the right time to be involved in clinical trials.

Infrastructure is not capable in areas that would otherwise be well placed to perform clinical trials and research.

DHB boundaries play into this issue significantly and restrict cross-border registration for clinical trials. In some cases, this has completely cut off access for rare disorder treatments and involvement in potentially life-saving trials.

Barriers to DHBs being able to accept patients into their region if they are out of the region.

As one might expect, trial activity typically goes to the big centres in the country which compounds the issue of access even further for people in rural locations.

Inequity of access for all types of clinical trials (e.g. some only go to the big centres so rural can't get access to medicines).

Large potential for participation and success, but no infrastructures in DHBs to allow for trials.

Even in some big centres such as Wellington there is a lack of infrastructure which greatly restricts the number of trials that can happen, thus preventing access for a lot of patients.

In Wellington, renal colleagues have no infrastructure for trials. Big population with a lot of Māori and Pacific as well, so chance for meaningful studies to be conducted but insufficient research nurses and hospital support.

Inequity between other paediatric areas that didn't have the ability to give medicines.

Ethics approvals have interdependence with equity issues

Ethics arose as a topic of conversation many times despite not being a focus of this project. It is clear, however, that ethics and equity issues have some interdependence. Interviewees felt there was a lack of guidance to navigate the ethics system, and no clear path to take to get a trial approved or in the best form to deal with issues such as Māori data sovereignty.

Complex review system called clinical trials with new regulations every 6 months. No support to navigate the system (e.g. Māori sovereignty issues but there is no guidance on how to do it).

Interviewees felt that the ethics processes were weak, and often not reflective of the populations they need to be serving (e.g. Māori and Pacific). Trials approved by committees may therefore not be asking the right questions for those typically underserved by the health system.

Ethics approval process, committees, pretty weak. Existing ethics committees have strong Western science-based value systems governing decision making. Doesn't account for

various Pacific values and perspectives when people are making assessments about the ethics. Potential merits and demerits of a proposal. Probably need more Pacific input into the ethics committees somehow.

Ethnicity data may be limiting in the way it is coded and could be compounding issues

Ethnicity data generally has limitations in its explanatory power and use based off the Statistics New Zealand and Ministry of Health classifications. Interviewees highlighted that the ethnicity indicator often aggregates populations which diminishes comparative power between populations. There may be further issues with this when looking at disease prevalence, needs, or appropriate treatment types.

Incomplete data situation in New Zealand—issue with ethnicity indicator, also often the data collection systems in New Zealand. Do not account for Pacific peoples. No Pacific person per se, but Samoan etc. No indication of relation to particular peoples.

Need to improve our [ethnicity data] collection systems.

Stats NZ and Ministry of Health may have taken the easy way out—a lot of people are happy to [be] multi-national but may be classified as one (i.e. Māori takes precedent over Pacific).

There are some examples of engagement with Māori, Pacific, and consumers, but not widespread

Māori, Pacific, and other consumer input within trial design and implementation seems to be variable, with some research groups generating and utilising more input than others. Some interviewees had quite explicit roles for Māori, Pacific and consumers in their trial design and conduct.

We usually have consumers on all groups set up (e.g. AI governance group); Māori health always included in governance and decisions. We think about what are likely to be the equity benefits here? Specifically, for Māori? How will they be involved in developing and co-designing?

We do think about equity though. We do have a CRP (consumer reference panel) some is about if number of tests is tolerable etc.

LiLCAS (Life and Living in Advanced Age, a Cohort Study in New Zealand) – one whole HRC grant, where there was no academic oversight at all. Went through to the communities directly to control. Resulted in [deleted] being employed early—co-leading heart core now. Māori PhD student trained through process as well, working alongside [deleted]. Development of people to get into research was a conscious decision—took a lot of effort, and co-development at the begin. Someone who is prepared to take direction from Māori, to develop it in the way they want. Must be acceptable in the Māori world as a pākehā where possible—can provide support, but a lot comes down to self-determination and drive from Māori perspective. Whānau Ora collective in Rotorua and Te Puke—going to finish her PhD on this project. Māori organisations doing this delivery, and now have an academic partner. Would never go to universities for collaboration before.

Our network has capacity for Māori and Pacific advancement through reverse mentoring and is active in developing a workforce and leadership.

Other interviewees signalled that they do not feel they have sufficient engagement, but encouragingly would like to do better to engage Māori, Pacific, and consumers in the design and conduct of trials.

Want to start a co-creation centre for older care. Panels of people in the community; not just the stakeholders, but the participants. Engage them first, and sometimes the topic change. Can be uncomfortable for the academics and an ego-shot, but there needs to be more focus.

Initial results showed Auckland had the worst long-term use of prescriptions for gout. We asked why do people not come into the clinic? Why do people not take the drug? Lots of stuff that came out—literacy, education, understanding of what gout is about and that it is a long-term thing. People borrowing medicines from their family members, stopping taking because they don't understand the nature of gout or what the medicine is doing.

We performed a laboratory-based clinical trial looking at Rongoā medicine in Kaitaia, and antimicrobial activity. We would love to do more in the community, driven by Māori practitioners.

Some use of prioritisation methods that consider equity, but not common

One of the most important ways for clinical trials to be impactful for the populations that are being served is to use a prioritisation framework that considers need and inequity of access to treatments. Some interviewees suggested they used prioritisation frameworks that consider equity of access.

We think about where we can make biggest impact at population level. Health equity impact and population impact then global burden of disease (e.g. top ten diseases and risk factors). They drive our focus.

Engagement of teams that are working with populations—if you are coming up with research ideas, make sure the research is important for those population (priorities).

These examples, however, are isolated amongst the group of respondents.

Some support mechanisms for Māori and Pacific engagement, but isolated

We heard there is some support for Māori and Pacific engagement, however it likely exists in pockets. Some suggested that their institutions have processes for Māori development and involvement in trial design.

DHB research office provides a central office that organises/provides secretariat for Māori review process (shared with Waitematā).

We have Māori involvement at the board level, which approve or don't approve recommendations in system.

The extent of the power these mechanisms have and the support they provide is unclear.

Others signalled that the mechanisms for supporting appropriate engagement and oversight are underdeveloped and currently being worked on.

Underdeveloped but have set up a Māori consultation group to try and expand links for consultation and development of relationship.

We have Māori and Pacific representation on the network but ongoing support has been hard to get.

School of Population Health in Auckland are shaping some rules about data governance for Pacific data. A process is underway about data governance. Very similar issues to Māori sovereignty regarding ownership, access, rules, permitted use.

Kaupapa Māori methodologies are not widely used or incorporated

There is an apparent lack of kaupapa Māori methodology usage within clinical trials. There is some consideration of kaupapa Māori methodology for the research context of their trials, but it is not a key driver of how trials are conducted. It may also be expensive and difficult to build kaupapa Māori research capacity.

Used indirectly in the research context but in terms of what we are actually try to achieve, doesn't have huge bearing on what we do.

Not really kaupapa Māori, more needing to get equal explanatory power for Māori, etc. and need partnerships to do that and for Pacific, but it costs about twice as much. There is additional work required between and during trials to reach these populations. It isn't easy, can be expensive and time consuming so have to be inventive on ways to find people in marginalised communities.

Looking to build this up, putting it in the work we do now, especially with PhD students.

We haven't touched on kaupapa Māori research, but it is a strong consideration to get more cultures involved in clinical trials.

Kaupapa Māori methodologies can cause delays in submissions and for international sponsors who don't understand the requirements and meeting them this is an issue.

As highlighted elsewhere, there seems to be an expectation of the Māori workforce to shoulder the burden of kaupapa Māori research and methodology even when they are not trained to do so.

Just being Māori does not mean you have the capabilities [for kaupapa Māori research] .

Māori and Pacific clinical workforce is scarce and what there is gets stretched

The consensus is that workforce capacity and capability to incorporate effective Māori and Pacific worldviews, needs, and engagement into trials is limited. Interviewees noted that the workforce is being pulled in many different directions and are overburdened with work.

Scarcity of Māori researchers – stretched thin and sought after.

This may also be compounded by the inability to recruit Māori and Pacific researchers.

Worried we don't have enough Māori or Pacific researchers to fill potential spaces.

Deliberate approach from university for the diversity – Māori and Pacific going through.

People versed in Māori advisory need to be attracted and recognised in terms of their time.

Some of this limited capacity may come from inappropriate training, as well as a lack of understanding of the requirements for effective engagement and incorporation of Māori and Pacific in the clinical trials workforce.

[Need to be] upskilling the basics.

Research organisations need to be aware of cultural safety to welcome research and organisations in. Role with cross-national science challenge Māori leaders' group. Released report 18 months ago—piece about protecting Māori researchers from double/triple roles. People going to them for Te Ao Māori advice whether they are versed in it (overburdened).

Trying to facilitate Māori to do research for themselves. Training their team already to take part in more meaningful way with their communities, from recruitment to sampling, publications etc.

Suggestions to improve equity in all aspects of clinical trials

Interviewees suggested a range of actions to address the issues highlighted above.

Focus on questions of importance for Aotearoa and the Pacific

There must ultimately be a focus on questions that produce meaningful results for previously underserved groups such as Māori and Pacific.

Focus on the impacts for New Zealand. We need to do the research in New Zealand for New Zealanders as it's not going to be done elsewhere (internationally) as we are the one that have a big burden. Need to look at questions important to us (e.g. rheumatic heart fever as it impacts on Māori and Pacific kids).

Growing trend towards qualitative research and the desire to improve equity go hand in hand and there should be more work in this area.

Thoughtfully framed clinical trials have the potential to improve what is available to people for healthcare.

Some interviewees also highlighted the interdependence of Aotearoa and Pacific nations and how that interdependence has impacts on health outcomes outside of our land borders.

People of Cook Islands and Tokelau are citizens of New Zealand. Treat them as if they are in the Wairarapa. We have an obligation to develop support and capability and capacity [in the Pacific].

Treaty of friendship with Samoa, Tonga, and Fiji. Inevitable that it is more of an inclusive approach.

No longer a case of us protecting our own borders—equally a potential source of threats to the islands. Measles outbreak in Samoa started in South Auckland. Increasingly interconnected—we cannot be oblivious. Explicit quantum of money in our aid budget for

island medical care. Samoa match New Zealand allocation for people who otherwise wouldn't get care in home countries.

Some see that there is already increasing awareness of the need to prioritise meaningful questions for Māori and Pacific, however it is unclear if there has been noticeable development in action.

Imagine there will be more of this going on (e.g. University of Auckland in their strategic plan being explicit about being more responsive to Māori and Pacific).

Use learnings from the data we analyse in Pacific health.

Pacific is just another step behind Māori. Need the scientific community to invest in them and understand that lifting the communities relies on culture. Not a lot of people thinking about this.

One interviewee talked highly of a situation where they were able to conduct a successful trial by making sure that the community were involved and fully understood what was going on. Once it was explained to the patients the importance of the work, they were invested and wanted to help.

Especially when new drug trialled; people kept talking about guinea pigs' issue (why do we have to have it first?). With commercial trials I was involved with, was amazing. Explained in detail how blood tests will be analysed and how it will not be used for anything else. Translated consent forms into Samoan, Tongan, got the pharma company to pay the interpreter who sat with the participant and myself to go through the consent process.

Equity of outcomes and high needs populations should form the basis of prioritisation exercises

Many interviewees suggested how the prioritisation process should work for including high-needs and historically underserved peoples at the forefront of clinical trials and research.

Always start with the intervention and trial designed around those with highest needs and populations that otherwise miss out.

Social license for the idea of participating in trials and creating the space for communities to say we have this problem, and what the trial should be about—what are the things that ail you? How can we help each other? (e.g. we know houses are cold and damp, why wait for a researcher to tell us).

Proactively consider inequity on the grounds of ethnicity and locality specifically. Has to be part of something, not a 'nice to have'.

Any trial needs to know the right questions, and the best ways of testing interventions, particularly for Māori and Pacific.

The trials need to be relevant to Pacific health—gout, diabetes, etc. People see the importance of what they do and what they can contribute. If rare and unheard of in Pacific, harder to sell.

Need to design for Māori-centric data to come out of it. That being built into multi-centre studies would be useful.

Some recognised this needs to be a top-down approach when setting the national health research strategy.

When New Zealand research strategy is being shaped ... there is a more generic question about enabling all aspects of society to be involved.

Seek input and advice from Māori and Pacific communities and focus on enabling participation

A key suggestion is to ensure incorporation of Māori and Pacific voice before, during, and after the trial to ensure effective participation and meaningful and equitable outcomes. Although only some specific mechanisms for this were suggested, the motivations were made clear.

Need Pacific-specific advice. Wrapping any project we are involved in with a Pacific community panel—have context with their various groups and communities, makes a massive difference. The Panel doesn't have to be big, but a wide range of perspectives that can bring a perspective to the work. Thinking about the questions through their lens.

People still have close ties with their islands and a lot of colleagues are still based there. Trials and research, colleagues in the Pacific areas must be part of the conversation. Should be applicable to the Pacific region as well. From experience, mini projects going on now. One example, hearing project in collab with some of the different islands (Fiji, Tonga, Samoa, New Zealand). Looking at hearing health in children. Little things happening, but nothing that is on a bigger scale. Pockets.

Engagement of teams that are working with populations — if you are coming up with research ideas, make sure the research is important for the population (priorities).

Need to think about how we get Pacific peoples involved safely. Need processes to inform, encourage, support.

Can use the DHB to try and find other researchers to help with Māori issues [e.g. networking].

Support processes for having conversations with communities in an authentic way.

Allowing patient/consumer groups involvement, if you have good involvement, then it makes it easier.

Some areas that may not have Māori researchers interested, but for whānau and community it may still be important.

One interviewee suggested that it is not necessarily about the number of participants in the process, but the quality of participation.

Consumer input could actually be less, but higher quality, that would achieve better equity than more, disjointed trials. Start with what is optimal, not with what we need to rationalise on.

Greater self-determination for Māori and the ability to use and incorporate mātauranga and kaupapa methodologies

The consensus is clear that mātauranga must be protected and utilised appropriately to ensure te ao Māori worldview is reflected in the design, treatment, and conduct of clinical trials, and not forfeited when participating in international trials.

Need to ensure mātauranga Māori is appropriately protected at a national and international level, and what this means for scientists looking to work in this area.

Mātauranga Māori protection, really making sure any funding doesn't go toward inadvertent cultural appropriation. Need to be clear about how IP is shared and looked after, access and benefit sharing. Real transparency, prior informed consent, dealing with these things outright especially when dealing with Māori communities.

There needs to be greater recognition of the effectiveness and validity of mātauranga in improving health outcomes and less application of western scientific methods to Māori populations.

Māori are capable of doing stuff themselves, need to be supportive of them to do that. STEMM programme (mātauranga Māori). Transitioned into a by-Māori for Māori organisation. Huge success for capability building. Within science organisation it is important to be setting out that area of cultural safety to retain some of the Māori organisations going in and being flexible about what their role looks like.

These mātauranga considerations can be applied wider than just to Māori as well and there can be coexistence of Western and Māori science.

There are basic relational things though like introduction and relationship building. Taking broader lens of engagement and values and being more flexible about new ideas and how you can progress in a meaningful way. Doesn't end when the trial ends.

Huge value in kaupapa Māori methodology for improving the health outcomes.

Māori will be wanting to show that the products for health purposes work in their own communities and tells an authentic story and helps their communities. Two perspectives can support each other.

Funders need to be onboard to prioritise clinical trials that will have the biggest impact on equity

The change must start at the top with the funding body to ensure the priorities of health research are aligned with the greatest needs for typically underserved peoples. Without recognition from the funding agencies there may be a mismatch in what they want to fund and what should be funded.

Commissioning agencies under the Health New Zealand and Māori Health New Zealand will be able to ask DHBs what is being done to advance health.

Funders will set priorities to some degree. Groups with interests will demand improved outcomes and money might be able to flow accordingly with the likes of Māori Health New Zealand.

Mentoring and increasing exposure by making it part of normal practice/business as usual is important for workforce development

Many interviewees noted the need for mentoring programmes to encourage Māori and Pacific researchers to undertake clinical trials and make clinical trials part of business as usual.

Make it something that is not as scary to the doctors coming through. Still in the too-hard basket. Colleagues will not touch because no exposure. Might not be for everyone, but people who get the exposure may take it on board.

Need a mentoring system or some sort of programme where we can buddy up with Liggins or something—spend time there, have it as part of GP training.

Having people to mentor and help—guidance for running a trial. Some supporting infrastructures to point in the right direction.

Professional mentoring is so important. Fourteen new Pacific fellows get their fellowship. Bright, young Pacific GPs working at clinics, calling out what else can they do. Research is a great arm—if someone can buddy and work through with them, would be great. Close to 80 Pacific GPs now in the College.

Others suggested teaching hubs where clinicians can become comfortable with conducting clinical trials and build capacity and capability.

Need to have the right connections, partnerships, collaborations. Want to turn clinic into research teaching hub. Very open to whoever wants to come in, do practicums, internships, projects, etc. If we can enhance these relationships, use different clinics and organisations as research hubs could start some of these trials and build on that. Teaching as we go, run clinical trials at the same time as normal work.

To be able to run mentoring programmes and increase capability and capacity there needs to be funding allocations and buyout of time to ensure research becomes a priority. The quote below shows this from a primary care perspective, however the same applies to most (if not all) settings.

Increase capability and capacity in primary care. We need to fund the general practitioners to be able to do this—fund them appropriately for the work they are going to do as part of the research process.

Needs to be specific, dedicated capacity for research in the practices to make these things happen.

Ensure infrastructure supports improved consultation, relationships, and engagement

Many infrastructure changes were suggested by interviewees. One envisioned a hub and spoke model to make clinical trials capacity and capability more 'liquid' and able to move freely around the country to break down locational barriers that may have previously prevented people from partaking in clinical trials.

Move to a hub and spoke model where they can move and away from a centralised institution in a fixed location as it can be a barrier to supporting equity and answering questions that come from communities that are underrepresented.

New infrastructure will provide a lot of opportunity to be able to show how important research is.

Some interviewees see a need for a nationwide approach in developing infrastructure, networks, and standards so that researchers have a sound understanding on how to design and conduct trials that are inclusive and have the interests of those typically underserved in mind.

Need a New Zealand Inc approach. Reform infrastructure and national standards so it is understood how to comply (e.g. Māori data sovereignty), we want to do it but don't know how.

Could have more systematic, formalised relationships with Māori providers and organisations—now very much on an individual basis.

Opportunities to improve Māori consultation and bring within HDEC. Systems are variable across the country.

Understand that relationship building takes time and should be a principle of a network when it begins.

Need more formalised way of prioritising the involvement and engaging the consumers. Helps it to be a bit more equitable too.

Funding issues

The summary issues identified to us are

- *Funding caps often too small for a trial*
- *The funding situation appears to be worsening as costs increase and funds don't*
- *The competitive pool is getting smaller*
- *Funders not keen on co-funding*
- *Soft money and continuity issues have a big impact on the research workforce*
- *Costing of research is often not accurate or complete or is inefficiently made to fit the budget*
- *Institutions aren't always playing their part in supporting funding of clinical trial*

Funding or lack thereof is a serious issue

Funding issues were noted by most interviewees as significant. A significant amount of time goes into funding applications and, when they are successful, they are generally regarded as too small for the trial work to be undertaken properly. Several stakeholders urged funding fewer trials with larger budgets.

You cannot fund a decent trial for \$1.2 million, in terms of contestable funding.

I have been arguing that fewer larger trials would be better than more smaller trials.

Funding one of the biggest barriers. Some success with HRC; in last couple of years has been frustrating. Competitiveness issue and only a certain amount of money to go around.

Thinks funding shortage is worse in NZ than elsewhere.

Funding size in NZ is small. And low success rate for HRC. Not enough money in the system and if in universities, they slice it down. Overseas colleagues can't believe we can do what we do with the funding we get. There is not enough money for the trials that should be done to inform policy. There is a lack of appreciation of the cost of doing clinical trials.

The quantum of money is not enough to be able to do the trials we want, and that are meaningful. HRC can fund multi-centre trials led elsewhere, but not reliably. HRC will not fund big stuff coming out of NZ that is meaningful.

There are very few funders and even fewer that can fund a clinical trial. Many can fund small studies for other work but not stretch to the required scale of a clinical trial.

The likes of Cancer Society only fund a few thousand, not hundreds of thousands. In the CT landscape, there is a real deficit of suitable places to fund those trials that the researchers want to do (there is a fragmented research landscape and large number of small funders).

New Zealand researchers may also find themselves in an awkward part of the funding market – with trials that are too small and, at the same time, not big enough.

Problem is that clinical trials seem to be resource heavy. Our current maximum project funding is \$80,000. You can do a nice piece of live research for this, but not a lot of clinical trials. This [clinical trials] hasn't been a large part of the funding portfolio because the funding required is often too high. It is always a bigger ask to do clinical trials. We have \$200,000 available for people now but will likely only be able to fund one. ... One problem of smaller funders is they don't have the evaluation mechanisms for funding the trials. One thing CTNZ does well is the evaluation process, have a committee. ... HRC is not the same as NHMRC; NHMRC is looking at early stages big research, and not what really fits for NZ. We do not fit in the funding criteria for a lot. We are not big enough for the really big funding, too big for the small funding sources.

Funding is needed to buy-out time

Funding means buying out clinical time to undertake the trial. Without adequate funding, there is no time buyout for clinicians which affects the amount of clinical trial activity going on.

Access to time – don't have the funding applied to be able to do the research. PIs are often stretched thin because of huge service components, next to impossible to do research. Need protected time to do research (often when the time is bought out, they still often maintain the same workload).

It all centres around funding unfortunately. [Funding needs to be] given to dedicated buy out and research time. There needs to be time to research and develop ideas. Speaking from non-commercial world, we need more funding to be able to do the homegrown NZ ideas and get them funded and through. More funding, more activity.

However, one stakeholder noted that, even if there is money for time buy-out, there may not be ability to do so as it is not easy to replace staff on a roster.

One of the funding things not working well is if I go and offer help to some trial, and suggest a time buyout, then it is not possible. There is no funding mechanism to give a clinical person time buyout to help with the university on the part of the funder and the DHB. It can be difficult to get back-fill for time buyout.

Funding is getting worse

For some, the issue of trial funding appears to have got worse. The shift to funding of priorities diminishes the pool available for competitive funding. This may not be smart, as the best ideas may not seem to be priorities but generally improve clinical practice, for the benefit of all, including in those priority groups.

[Researcher name] currently has one study with no grant, low budget. Other studies are getting paid much less than previous years. This is affecting our financial manageability. Work more, pay less.

Isn't enough money and the pool for research that is competitive isn't big enough. Currently the increase in funding is more toward initiatives that are driven by identified priorities. Priority funding grown; funding not grown for the other competitive pool for

general research. ... More contestable money, no pre-conceived idea of what should be funded. In the past almost all was contestable, now govt. decides.

Money itself hasn't increased disproportionately, but the contestable fund has decreased.

Costs are increasing

The costs of running trials are increasing at the same time as clinical trial funding is felt to be stagnant or falling.

For most RCTs, whatever the cap is (\$1.2m or something from HRC) is just not real – costs increasing and caps staying stagnant.

Creeping privatisation makes CCDHB hard to do trials. Labs are being privatised – I used to be able to do stuff at cost, now the costs have gone quite extreme for some of the labs. It is critical that health boards and HNZ have specific provisions for research as a key activity to access low-cost services. Three services that fall under this – radiology, laboratory, pharmacy. It is sometimes more efficient and easier to in-source that.

Responding to tight funding

The funding issues highlighted to us seem to have a root cause in a too small budget allocation from the Health Research Council in many instances. Researchers report that they take what they can get from the funding available but that this is often not enough. There are several responses to this too tight funding:

- The trial sponsor will seek to top-up funding for the trial from other sources particularly philanthropic funds. However, researchers noted that most funders are not happy with co-funding and the opportunities do this may at times be limited.
- Less helpfully, the investigator may seek to pursue the trial even though there isn't sufficient money to answer the question. Statisticians noted to us that this is often simply a waste of time and money.

Operating on risk margins of participation and drop out that are unacceptable, and arguably unethical.

Ended up with funding structures that are highly risky in terms of performance and achievement – builds safe practice, not necessarily good research.

HRC failed his latest one, but then received funding from the college. Way less than HRC funding and didn't cover overheads, but still managed to go ahead.

The issues are most acute in primary care clinical trials

Stakeholders in primary care were highlighted that the issue of clinical trial funding in primary care is particularly important in supporting equity goals but is lacking. Primary care is over-committed and over-worked and there needs to be clinical trial buy-out of time if primary care were to be able to participate in clinical trials.

Funded time to run the trials is a barrier. Funding for time to be able to do this sort of work. Currently some funding to draw people in to doing clinical research (shoulder

tapping by unis). This is not done in a systematic way, but there is not a strong model for funding research capability and quality improvement and developing skills for community based research or academic leadership. It is very ad-hoc – creating a research strategy could be the way forward and how to develop these skills. Let's get the funders onboard, prioritise clinical trials that make most impact on equity, increase capability capacity in primary care for this.

Our funding environment has always been restrictive for primary health work. In Australia, the UK and the US, there are so many more opportunities for funding. There is a split in the UK to develop NIHR was significant for health services research. Boards funded lots of trials. People got good work done in aged residential care. You are doing work in the non-exciting areas of healthcare, but important, nonetheless. A comment in feedback for a dementia trial application – what's the point? Got dementia already. [This attitude] applies for everything – got a few AMRF things, some lotteries money as well. Universities fund a little bit. Trying now to get philanthropic funding too ... ythose that are good at schmoozing get philanthropic funding.

Continuity of funding makes life difficult

Funding is largely episodic meaning there is little appetite to take a risk on capacity funding of research resources unless the organisation is one of the lucky ones with an established trajectory of clinical trial opportunity and prospects. the flow on consequence is that it makes it difficult to build and retain capacity whether it be Senior Medical Officers, statisticians, data managers, research nurses, let alone facilities and IT. The investment model is as struggle to build.

One of the challenges is that the funding models we use are almost exclusively or predominantly episodic project-based funding. It is more challenging than ideal to develop consistently funded professional staff, and to have the confidence that you will have their institutional knowledge day in and day out (i.e. don't have to keep getting people in).

Process of doing research that you need to have the experience of and is hard to continue a research programme without the continual research capacity.

Would be great to have the continuity in DHBs as well as universities. We have a well-oiled research team, all over GCP etc. – move from one to the next. We don't have that in DHBs.

Funding goes hand in hand with systems.

The money for the trial might be sufficient but there is a loss of momentum if there is need or benefit from follow-up trial work.

Trials-level of funding of \$1.2m seems to be workable, but there is no fat in the budget to do anything either side of the trial (pre- or post-work). You always have to apply for funding for extra, and therefore lose a bit of momentum with follow-on trials as cannot do the post-work when wanted to.

Translation of findings into clinical care is often slow because of the funding system. There is not funding allocated for post-trial follow ups or implementation.

Takes 17 years on average for research to change clinical practice (anecdote) – interesting because probably true. [Translation] to some extent driven by the grant system, don't have the resources for follow ups. Incentives are perverse – grant system drives you to the money and not necessarily where the meaningfulness is. Cannot see it right through to the next stage often, can lead to a lot of competition between institutions.

A serious flow-on impact to the workforce

The lack of trial funding means there are only a few groups that have continuity of staffing and those staff are often living off project money, with no certainty of continuance after the trial completes. Any that had roles, were only funded for part time roles, such as two tenths employment in clinical trials.

The effects of having less money that desired impact on all workforces with some of the specialist inputs being unhelpfully squeezed on time:

- Because funds in the trial is limited, statisticians highlight that there is an expectation of their being able to undertake the work without appropriate funding. They find that they are often limited to a very small sum of money and therefore of time, and either have to cross-subsidise from elsewhere, or from their own time.
- Statisticians are squeezed but health economists are placed under even more pressure and likely not included at all. We identified only one health economist with an ongoing clinical trial commitment and resourcing.

Piecemeal funding for public good research means we can't retain staff as only 3 years contract etc then finished. System favours the big ones and stifles new ideas etc. It comes from DHB lack of funding and can't get research staff.

One hospital noted that it was fortunate in having dedicated resource for public good research, as the research was part of the standard of care for the organisation.

[DHB children's hospital] has some hard funding for clinical research people who bring clinical trials into the hospital. There is a network of people across the country, pool their resources. Between us, we allocate the workloads with opening and conducting clinical trials. Most of the studies [a researcher] referred to are collaborative group studies, rather than pharma studies. Generally, most paediatric oncology treatments have gone through Phase 1 and Phase 2 in adults, before being given to children. The numbers are small, so not commercially viable often for pharma in children. There are groups of Primary Investigators such as the children oncology group – and other groups with similar functions. They collaborate in these group trials. Some pharma ones happen – sometimes give fast-track to medicines and complementary to the studies done but it does not take priority.

Institutions are not playing their part?

Researchers note that HRC has its role as a funder, and other institutions have their roles in the clinical trial eco-system, and they may not fully acknowledge or operationalise that role.

HRC has its role in funding, paying out time, but the institutions have a responsibility to allow the research to go ahead as well; the time, the workload etc.

Universities are an expensive way to undertake research

Researchers noted the significant leakage of research money to the university. The money goes much further if the trial is undertaken in a DHB or other environment because of the high overhead charge levied by the universities.

Always an issue, trials are expensive despite their nature. University trials make it more expensive with overheads.

Universities can be disincentivising for research when they top-slice trial funding for overheads. Chooses to do trials through Dunedin hospital for this reason.

This reflects general confusion over overheads and what they pay for, or don't pay for.

Re: overheads; no matter how it arose, we need to consider now and the future. The system is a muddle, where some are overhead, some cost-recovery etc. Where we do have overheads, they should be invested in the research provider research-ready for the next contract. Investing in support for building capability in research by and for Maori and Pacific people. Strategic purpose for the overheads, but also some for the heat and the light etc.

DHBs have a role in releasing resources

A stakeholder reported that there is confusion between some aspects of buying out and is the responsibility of health sector organisations in supporting and sponsoring clinical trials. Unfortunately, some DHBs see the value of clinical trials and actively support them and others don't.

When funding is coming into trials, what is buying out, and what should be embedded in the sector itself as a product of engaging in research?

In DHB-land, ask what value they are getting from overheads? Makes them non-competitive compared to privately funded. In pharma CTs, generally end up with transactional contract with line items very clearly sorted out – offers some uncertainty.

Those institutions also have unfunded roles

There is other institutional activity and assets used in research which are sometimes not fully recognised in funding or in funded research. One stakeholder pointed out that the cost of biobanks, repositories and collections are all part of a clinical trial ecosystem that needs to be funded.

Lack of funding could be leading to inefficiency

One stakeholder made the important point that the lack of funding may mean that the right mix of staff are not used on clinical trials. Some tasks may not be done by the best person for the job. One stakeholder compared this unfavourably to the situation in the United Kingdom:

NIHR has slightly different funding models that are more supportive of research staff. I think that universities and DHBs are not great in NZ at strategically identifying the best way to utilise human resource. How to have each member of team running at optimum? For example, having sufficient administration support for academics. Sufficient IT support. ... Try to be strategic – make the time best spent. What can be offloaded? Shouldn't be

that everyone is driven hard, more about whether it is best used. From university and DHB perspective, time is almost treated as free.

The process of grant seeking may also be leading to bias in proposals and untimely approvals. On the one hand, sample sizes offered up in proposals may not be realistic.

Sample size – one of the concerns. Very common for trials to have extremely optimistic recruitment size, or how sick, or how many Maori and Pacific they will recruit. People feel they must have good looking figures for grant proposals – not a lot of audit of this.

Or the HRC funding may be coming through too late for recruitment and analysis.

Several studies seen recently by [a researcher]; recruitment was so delayed that the HRC funding finished before recruitment. I haven't even got data when the funding is finished. If a lot of studies happen like this, it can become problematic.

Application processes are time-consuming and demoralising, and haphazard

The idea of a competitive pool of funding was not seen as a bad idea, but the size of the pool or other commissioning processes were unnecessarily difficult. Competition was a fact of life.

Generally, think a competitive pool works well, and that people are driven by want for good research, not just to qualify for funding for meaningless work.

Must be prepared to fail and try again and again with proposals – persistence of effort to funding.

Sorting out money for trials can be a long and demoralising process. Sometimes, the idea of a trial is taken up by the funder and then commissioned through a competitive process, with the originator of the idea then having to compete, and possibly not winning. The process of grants seems to work better although it would be better to see a programme of work rather than project specific grants.

Ministry of Health trials can be quite difficult to sort out funding, for non-HRC and trials focused funding. Overheads and its requirements are often different and it can be a hugely time intensive process to put in proposal. I worked on a Ministry of Health trial application for over a year but didn't win; they gave the trial (this stakeholder's idea) to someone else.

Don't think the funding system properly makes money available to fund trials. Haphazard – lucky if you work somewhere with the infrastructure to support the trial. Might therefore be able to run a trial. For things people otherwise would want to be able to do, there simply isn't funding allocation for.

Proportion of grants to be funded is quite low – put a lot of effort into the proposals and often for no return.

There are considerable network effects in the ability of researchers to compete. Researchers who are starting out or working in other fields might struggle to pull it off.

Have got the critical mass to be able to put the proposals forward, but this is not across the board; isolation is a problem. If you're the only person trying to do the research in

that area it can be really hard to get it up and running. Not quite the same thing having collaboration over large area as opposed to your co-workers right next to you (network effects).

The application process for HRC grants is further compounded by the approval process, which is seen as unnecessarily hard work.

The admin burden for HRC grants is ridiculous. There are about nine steps to get there with all the approvals and will be also for multiple sites so nine times sites. There are multiple administration hoops to get through. DHBs all vary in what they have and there is no coordination or standardisation across DHBs. Some will accept other DHBs but others won't. It is frustrating.

Some suggestions on how to structure additional funding

Several stakeholders made a few suggestions about how to structure funding particularly if more were made available. There could be funding of centres of excellence, or funding of recruitment, so Primary Investigators could move from advisory roles to active participation in international trials.

It would be good to have operational funding for a series of clinical trials centres of excellence and, secondly, funding for NZ to recruit for overseas trials i.e., a contributor to join trials. OZ through NHMRC have this. We don't but can get through HRC or Heart Foundation, but it takes a year.

Another suggestion was to think about partnership grants with DHBs and this may be a better way to both resource DHBs and, also, mitigate monitoring costs for HRC.

When I am thinking about the HRC current move towards funding of health delivery, [this could mean] partnership grants with DHBs, with HRC moving into the development of funding infrastructure and research capability. The HRC process has been very poorly executed, and I am not convinced it is going to deliver the benefits we hope for. I have not seen any progress reports, funding announcements etc. I don't know that they have the resource and capacity to support the activation grants in the way it was supposed to. And DHBs have likely put stuff in that needs a lot more resource. I suspect the funding would be better coming from commissioners with clear expectations of how the money is at work and what needs to be done with it. HRC could then focus on investing in research excellence and the support system.

Information governance, management, and analysis

Our current state:

- Limited awareness of sovereignty issues, little practical activity, few sources of guidance.
- Practice in archiving data highly variable.
- Data management roles range from informal (both pros and cons with this) to quite formalised, but there is little formal training and no career path
- Systems are evolving. REDCap is reasonably widely used, there are fewer ad hoc spreadsheets and Access databases.
- The data manager role is not always resourced appropriately and generally is supported by fixed terms contracts at best or project money at worst.
- Despite this, the NHI provides a head-start to most countries.

Data management processes are variable

Several stakeholders noted that it would be helpful if there were a national approach to storing data securely, referencing commercial trials data capture systems as something that they would like. One DHB research office noted Excel (a spreadsheeting software package) is used a lot for public good research. The ability to share data across organisations even for the same trial can be difficult.

Need to focus on data as a key foundation of research rather than just the output.

For some, they come to data management as clinicians, which is helpful, as terms are easier to understand. Generally, there is differing levels of experience and data management expertise across the team and learning is on the job. There is generally funding for the statistician and data management if the trial team has been clear about who will get hands on with the data and ensure that it is cleaned at the end of the trial.

When I started, the position was within the stats group. The position was created because statisticians within the group had a vested interest in better quality data capture. There is significant overlap in making sure they [metadata and datasets] are well designed in the right way to ensure less cleaning up at a later stage.

One stakeholder noted that there must be a process around data reviews, randomisation, and ad hoc issues that pop up throughout the trial.

The role of the statistician is sometimes underestimated, and they may be brought in late to a trial even sometimes after trial design. This situation seems to be improving although there is still a sense that the role of the statistician is undervalued.

A decent proportion of the trials have a designated stats support from within the group.

There was general concern that the role of statisticians is undervalued, and the role of data managers even more so.

If statisticians are undervalued, then the data managers might be even worse off.

Probably these days is a bit more understood that it is essential for application, but often data management support is still skipped or overlooked. It is not given the same profile as statisticians, and I imagine it is probably common to other similar units.

Statisticians see the role of the data manager very clearly.

Statisticians different are different – they try and encourage data managers to be involved from the beginning. They are involved in grant applications, are very much closer to the team and design of the trial, safety reviews, analysis etc.

There was some discussion of how this awareness could be changed, starting with the medical school curriculum. There is a general feeling that this would be quite difficult – “I have a lot of trouble teaching people basic statistics”.

Clinical Trials New Zealand are an example of good data management practice

Several stakeholders identified that some organisations provide good data services for themselves, and one that was identified was Clinical Trials New Zealand. For instance, there is a new laboratory information system which has all the patient and lab study data on it. This is MS SQL database on the patient administration hospital system, which everyone can access, and with a single linked database.

Prior to that, the trial team made do with standalone databases and spreadsheets. Prior databases weren't linked, and therefore there could be five different copies of the same person.

There is a dedicated team (of three) building databases and undertaking data management for all the projects.

One of the biggest parts for us was investment in commercial eData Capture Programme in 2017 which has enabled us to efficiently deliver database side of CTs for all the projects that come through

CTNZ points out that it is not just building a database, but also about having strong controls around it and ensuring it meets protocol specifications

CTNZ reports that it has a relatively small team and has structure around project management and data management. Attention to communication within CTNZ ensures data capture is well communicated at all levels of clinical trials (i.e., project manager, investigator, RNs, etc.)

Might be because we are small and can come together every so often to discuss and keep an eye on it

REDCap has become the primary tool for data capture in New Zealand

Several stakeholders identified to us that the user model has meant that REDCap is used across the country. Everyone generally supported the move away from Access databases or, even worse, Excel spreadsheets. The benefits of REDCap seem to be its availability as a web version, or on a server, ease of data capture, extra features, ability to interface with other applications and is regularly updated. Importantly, the software is free to not-for-profit organisations.

It is helpful that REDCap is the primary database now. We are able to compare things and support each other more easily

Compliance with clinical practices. REDCap has features to track things and data changes and does the job well. So many features and continuous updating (come a long way).

The real difference isn't between the good and very good systems, it is between anything and Excel. There have been some bad experiences with Access too – could be Microsoft that is the issue.

REDCap is free, continually updated for not-for-profit work, can be stored on premises, and is web-based. There are extra features available too; online forms, emails, etc. We have the complete package which makes it attractive. There are active userbase feeding back into it.

[One data manager] has been using REDCap solely, so much more cost effective and flexible. Quite a few groups in university coming to us for REDCap knowledge and external consulting. It is easy to extract data from REDCap

Other tools are used for other purposes. As one data analyst highlighted to us, there is Stata and R for data manipulation and analysis, Power BI and Tableau to interrogate databases, REDCap for capture of data, Salesforce for participant management, Florence for trial master files, OpenSpecimen for lab side of things and collection of biospecimen data (smoking rates etc). Sponsored trials have Case Report Form tools provided.

A series of improvements

Challenges reported to us by stakeholders include:

- There is not enough importance put on the data to be collected nor is there enough planning for the data. PIs are not necessarily receptive to the message that there needs to be a robust data system. Little funding is allocated to the activity. The planning needs to be early on in the trial design.

Not much going into the budgets for any kind of data stuff. Started allowing a little bit for the people but struggled to find the funding for their system.

- Funding is tight (if not there at all) even though data management is a small part of the trial. Some of this is because trial funding has not increased at the rate of the cost of running trials. Sometimes project leads may squeeze the budget for data management, choosing inappropriate but less costly tools.

Funding needs to be multiplicative (feasibility and importance of the question) – doesn't matter how good the question is if the trial cannot answer it.

- Needs to start from the start – data capture must be good and engrained at the beginning. Good capture means good outputs, bad capture means bad research outputs. Future funding is dependent on past trial success. High calibre input is vital at the start.

A lot of it is when it comes to designing it – a lot of the people involved don't necessarily have data management skills and capture, introduces a range of issues and headaches down the line when it comes to cleaning, using the data etc.

- There are issues of sustainability and continuity of data expertise particularly as the positions are generally project based and not long-term. Cover is difficult to organise as

the resource is slim. This emphasises the need for well developed and well documented tools, but this is not always the case.

- Networking amongst data managers could be strengthened as the university-based groups tend to get isolated and possibly out of touch with technology and best practice.
- Research and DHB systems are very disconnected which makes co-analysis difficult as well as making it hard to share data. Even with patient consent, it is very difficult to access data. There is no common security framework meaning that each party needs to verify security and certification before data can be exchanged.

Hard for people to connect from a research point of view. Sharing and co-analysis hard to do.

- Training is a motivator as well as an issue. This is in sharp contrast to other industries where credentialling and ongoing training is used to strengthen the profession.

Training other issue – if people are well trained then they will be more likely to stay in the industry. Is a big barrier, especially people who don't think they are developing professionally – might take other opportunities and further their education and roles

- Training is fragmented and generally not supported around data systems. There has never really been any formal training in clinical trial data management. Generally, people just muddle through.

Having modules of training which can give the bigger picture, or some national diploma or something would be a great facility. Micro-credentials. UoA proposed post-grad DM course. If that goes through, might be in 2023 that it would start.

There is a general worry about activity that is happening and whether it is all up to scratch. This comment, although from only one stakeholder, is worrying as it raises issues about social license to conduct clinical trials, if there are systematic concerns about the robustness and professionalism of approach.

There is a lack of transparency of what projects are going on, and what methods are being used. Transparency builds trust, robustness, participation, etc.

There was mention by some of positive examples that New Zealand might follow such as Swansea in the UK, Monash in Australia, Safehavens – SERP (secure eResearch platform). There might be shared notebooks such as Jupyter notebooks, Codespaces, etc. This could be achieved in a federated systems environment allowing researchers and data managers to retain a degree of control.

The funders could be a lever to ensure that there is the correct funding allocation and expectation of data management services. Funding bodies could issue guidance around the types and levels of data quality required for the project.

Several suggestions around REDCap were as follows:

- Training particularly in REDCap could be organised better. One stakeholder noted there is a REDCap users' group in their university because there is no formal training available. IT support is not available unlike for other programmes.
- The form filling function on REDCap is less than desired and several stakeholders identified that they want to combine features of Qualtrics to improve this functionality
- The full functionality of REDCap is not used.

People should learn coding. REDCap allows you to extend functionality through custom scripts – helps with projects and what you are capable of.

Stakeholders note sourcing primary care data is particularly difficult as it is not held in uniform manner across practices and is not extracted on a regular basis. It is not uniform across different practices and everyone is coding differently and sometimes not at all, e.g., for nurse consultations.

One stakeholder noted that New Zealand is small enough that we could have a country wide research platform.

All patients across country can opt in and out and can use the data to cover multiple different areas quickly and easily.

Data curation and storage is variable

Stakeholders generally agreed that data storage tends to be ad hoc. There is little in the way of guidance and awareness is poor.

Our approach is fairly ad hoc. We make some efforts to get people to pick out the really important valuable stuff

Researchers are not given a document on how to run good data governance, and if they have good people around them then they will be able to do it, but otherwise no one really has any clue or training.

Things have a bad habit of sitting in file servers as they were left when people stop using them.

Several stakeholders noted that increasing use of REDCap had its advantages.

Much easier with REDCap now, can upload files (try to input everything at the end of the trial) and can stop data entry and archive it.

Some clinical trials networks are well organised. One clinical trials network noted its MS SQL database is on the DHB IT system, so stays there. The database is getting much larger and the DHB takes charge of back-up and recovery. Studies must be decommissioned then are backed up. There is strong custom and practice about accessing data although there could be more formal Standard Operating Procedures.

Can look up old trials and the data from it – don't normally archive stuff off so that it can be accessed still.

Capability in data management is hard to grow

For others, one of the biggest issues is the capability to manage data.

Successful people have people who have worked with them a long time and have managed their data well. It is a predictor of good success.

The capability is hard to grow if you don't have it. Several stakeholders acknowledge the relationship with statisticians is often undercooked in clinical trial design and implementation which compounds

the problem. One stakeholder called out university systems as not enough having data management and statistics capacity.

Universities well supplied with equipment etc. ... just don't have the people.

People fall into the roles ad-hoc. Hard when working in a clinical environment to get someone with clinical understanding and the technical expertise for the database management.

Generally, those employed lack one skillset or another and are trained on the job. An IT skillset is useful but difficult to find as there are other better paying roles. Once trained, the role is a niche role within clinical research and there isn't any career path other than with industry. Contracts are generally fixed term.

Isn't anywhere for career data managers to go aside from industry. Very compartmentalised – go into niche roles within clinical research and data management.

The kind of work that I do, people find their way in without any specific plan to do it. Find themselves working in data, and then decide to go specialise there.

All on fixed-term contracts. Generally, 1-to-2-year contracts. Boss who has been there 35 years only gets 5-year contracts. We're reasonably fortunate where we are that we have a fair amount of confidence in the stream of work coming our way. Not a lot of instances of having people move on because cannot support them.

Mixture of funding – work full time and there are 2 other full time. One who works 0.6. One of the full-time, has 0.5 core funded, and 0.5 from particular trial. The other full-time person has 0.5 from a trial, 0.4 from another, and 0.1 from elsewhere. The 0.6 one has no core funding, and basically his position gets paid for via cost recovery work, either by himself, or by the other full timers.

Organised in different ways and sometimes not at all

The data team or person is integrated with the research team in different ways. At times, the statistician takes the role of the data manager as well, as the person most likely to incur the costs of poor or untidy data. In other instances, the data manager is a small full-time team or a part-time resource, as part of the clinical trial network or research organisation. At other times, the team could be organised as an arm's length consultancy for research teams.

Our team is data managers will often be consulting with people building database, giving them advice on how to resolve problems and do things better etc. Sometimes people with money will come and get someone to do the build work, and they do that on a cost recovery basis. Sometimes, fairly rarely, (there are two to three trials like this at any one time), they will contract a data manager at 0.5 FTEs that will take charge of the database and do the quality checks, consistency checks, etc.

[The position] exists off to the side a bit, partly because the unit has stats researchers within it as well. Bit of complexity here. Within the last few months, a separate team being developed in the office of research – developing data management group.

Data could be more standardised

There could be more standardisation of data collections. There is a need to be able to pull adverse event data from hospital systems. There are timeliness issues around registry based clinical trials. It could be easier to access NHI database information with ethnicity and gender.

There could be stronger governance of data standards, with all health organisations working towards nationally and having consistent datasets, with clear guidance for on, for instance, sex and gender.

Data for Pacific peoples are regarded as incomplete largely due to issues with the ethnicity indicator making it much more difficult to benefit from any gains in electronic health records.

The range of available data sets is set to expand greatly

The complexity of data has been increasing and is set to increase further.

A lot more technologically based studies now that have complex data forms. Coming from a lot of different sources, becomes more complex to manage.

The general consensus is that the health data system in New Zealand is good from a researchers' perspectives. The National Health Index allows linking of health contacts and the national collections are useful. The major gap is in primary care data and there is not much of a window into clinical activity and events in that part of the health sector. Primary health care data is not collected or put together nationally in a way that would be easily collated. There is no incentive to get a standard set of information unlike in the hospitals. Laboratory tests access for clinical trials exist for the three Auckland DHBs but not, it is believed, elsewhere in the country. One researcher noted that primary care datasets are an "amazing" addition to hospital datasets particularly for any trial involving aged care, rehabilitation and other topics.

Different companies doing it that don't necessarily play nicely together.

Electronic health records and the wider digital infrastructure initiatives show great promise to enrich some aspects of clinical trials. There is a general feeling that the pace of change is increasing in digital infrastructure and the opportunity to link administrative and clinical datasets. A few stakeholders noted the usefulness of the National Health Index and several also noted the Integrated Data Infrastructure. The Integrated Data Infrastructure, they note, may assist with greater access to a wider set of social services data. Several stakeholders saw this as an important point to leverage, better inform and more fully connect across a wider range of datasets at little cost.

Linked in with social and other data, form the IDI which is linked at the individual level about work, convictions, etc, which can be useful. If there was a clinical trial database that linked in there may be no practical reason why this couldn't be integrated.

There might also be opportunity to look at some of the tools used in integration of care, with a particular focus on clinical pathways. Some of this is being done now but it could be extended to other geographies.

Need to open some of the clinical trial data at tertiary and secondary care. Don't have good visibility about the clinical pathways within a care environment. Waitemata is doing good work following people through clinical pathways – could standardise this approach.

Currently, however, there are issues with availability of data

- It is hard to access primary care data and there is no systematic data extraction.
- Sometimes, there is a lack of coding data particularly if the patient does not come to the hospital. In that case, there might be a need to find an artificial intelligence company to read PDF format outpatient files. Those companies are not fully trusted.

One stakeholder noted: FIHR (an acronym for Fast Healthcare Interoperability Resources) means data can be connected more easily, through Application Programming Interfaces, that clinical functionality is increasingly paper-less and systems increasingly aligned. The implementation for this additional step is planned and underway. Equally important are the institutional arrangements that ensure access to such data is appropriate such as the arrangements in place in with HealthOne in the South Island.

One suggestion is that there could be co-governed breakouts of data. These breakouts would reduce co-ordination issues around data whilst, thus facilitating access, and would also preserve data security.

Need a different system – should be based on co-governed data sandpits; environment where individuals can commit their data to the sandpit, and pre-approved people can access it for use. This would be a safe data environment where data can go in, and could be anything. Sort of works, already there in longitudinal data, but the sandpit set up for a particular project and wider environment could work really well with good governance.

New R tech – moving away from requirement to bring data together. Data stays at source, code moves around at multi-level permissions. Don't have anything like this in NZ – need a national approach to health data as a strategic resource. AT&T use it all the time at scale, 120m units.

With all the data systems described, we have some of the best linkable data in the world. Costly elsewhere, government system and chief data operator is an opportunity no other country has. Can be internationally significant data resource.

Data sovereignty is a live issue

There are complications accessing hospital data and uploading it to clinical trials systems when the system is shared internationally. For instance, one stakeholder noted that one of the trial sites wanted to upload ED data to a REDCap database. This was extremely difficult particularly when other sites including the US can access the direct link to hospital systems data.

Several stakeholders raised matauranga protection as an issue, meaning that clinical trials really need to make sure any funding doesn't go toward inadvertent cultural appropriation. Those stakeholders noted that any institutional elements of clinical trials, whether providing clinical trial services, funding clinical trials or regulating clinical trials, need to be clear about how IP is shared and looked after, access and benefit sharing. Those stakeholders advised there needs to be transparency, prior informed consent, when dealing with Maori communities.

Maori capable of doing stuff themselves, need to be supportive of them to do that. Research organisations need to be aware of cultural safety to welcome research and organisations in.

Some clinical trials networks and other research organisations have directly and proactively addressed the issue of data sovereignty.

We have an on-premises data server for REDCap for sovereignty reasons. Can have it on cloud but choose not to. Have Maori data manager with the oversight – very precious and rare advice and position.

Others noted data sovereignty is being questioned more now than before but the questions are difficult to answer.

Problem for [...] is that no one body or group has a good definition of what sovereignty is. In some cases if no one external to the country has access then it is fine (even if stored overseas). Other interpretations limit it to being stored in NZ.

For others, data sovereignty was not seen as an issue, or might be an issue they are aware of but do not have the capacity to address or

“Data sovereignty is probably not an issue for us. We are aware of it. There is ongoing discussion as to how we manage it. It hasn’t impacted very much on us.”

Occasionally hear about engaging participants and communities in research activity but haven’t come across directly.

I am engaged in conversation about how we can best support people to follow best practice and not miss-identifying data with research data. We try to maintain the separation. It is pretty common for people to lump their data together. I try to communicate to people to keep the data separate.

Engaged in convo about how we can best support people to follow best practice and not miss identifying data with research data etc. – I try to maintain the separation. Pretty common for people to lump their data together. Try to communicate to people to keep the data separate.

Area that would love to be able to do more, but don’t have the capacity.

More infrastructure could help

Centralisation is unlikely to work as there would be disadvantages in local cooperation. On the other hand, parcelling bits out of partial grants doesn’t work. Possibly, there could be a pool where skills are short, such as clinical coders. Or there could be long-term stable employment offered centrally but operating locally.

Possibly, there could be accreditation of clinical trial groups, that would ensure data management standards are met.

Standards come up repeatedly for security, data, as do guidelines. The process of developing and implementing those standards and guidelines was identified to us as important.

We will need local data storage capacity here, for a range of intellectual property and data sovereignty issues.

Challenges with workforce capacity and capability

Our interview analysis has established that there are numerous challenges with workforce capability and capacity with respect to clinical trials. These range from high-level, health-system wide issues, down to the individual level and their desire and ability to partake.

Research is not a part of health care culture in Aotearoa – involvement currently comes at a cost to other responsibilities

The highest level and most common issue brought up by interviewees is that research is not treated as a core component of health care in Aotearoa.

Challenges are ... around how research is valued and embedded in the sector. ... Around how the workforce is enabled to participate in clinical trials. Systems and cultural problem.

[Clinical trial] activity that occurs is at departmental or individual level – driven by people who want to do research, not the DHB itself.

Less than 5% of surgeons would see it [research] as part of their role.

Generally are opportunities to be had but held back by the make-up of the health structure as research is not recognised.

NZ doesn't consistently experience support for the philosophy that research is fundamentally important for healthcare.

[Specific] DHB views research as a hindrance to the function of the hospital.

[Clinical trials] not high on the radar or KPIs that they need to meet.

A dichotomy exists where people with medical appointments are expected to research, however are not funded to do so, or are expected to do it off their own back. Involvement in research largely comes at the cost of other responsibilities and activities, whether that be in the workspace or in peoples' personal lives.

People perceive they don't have time. Their ordinary responsibilities and administrative time consume all spare. Those who are at private [hospitals] may be busier and have less flexibility. Often no space to resource the research.

Access to time – don't have the funding applied to be able to do the research. Primary investigators are often stretched thin because of huge service components, next to impossible to do research. Need protected time to do research (often when the time is bought out they still often maintain the same workload).

Time spent on clinical trials far exceeds time [allocated] – puts pressures elsewhere.

Do have people who are enthusiastic, but at huge personal cost.

Clinical demands have increased so less time for research. On the side same in academia, the teaching [responsibilities] etc. has increased.

There are some examples that give light to the spectrum of clinical trials activity in Aotearoa and the degree to which they are embedded as health care practice. Interviewees involved in child oncology made it clear that clinical trials are an essential mechanism to providing appropriate standard of care for their patients, and the culture of their workforce is to promote and undertake research.

[In] paediatric oncology, clinical trials are essential for clinical care, otherwise wouldn't be able to access these treatments. Define a culture of care in the unit. Vast majority of them are created overseas – generally too rare to get a good cohort in New Zealand. Takes a lot of resource to open, review, and conduct clinical trials. Enormous amount of networking from when the trials are conceived so that New Zealand and Australia are thought of in the design process. Lots of resource for ethics and going through them.

Contrarily, in primary care settings clinical trials are often non-existent because of general practice business models, bare minimum resourcing to provide patient care, and a lack of knowledge about the research process and how to partake. These effects are likely even more significant in rural settings.

Having been consulted many times about the clinical trials, big task to run yourselves, and GP are already really busy.

Need understanding of how clinical trials are run, what is involved, and knowledge of clinical trials itself is a good thing. Need people to feel more confident about [partaking in] clinical trials.

Often people [who] end up in rural places are more hands on and less academic background. Can be feeling of a lack of skills and confidence. No statisticians, data management, ethics support etc. in rural places need access to from other places.

[Important] gauging people's interest to do research as they may not be aware of it as a possibility. I did it here [rurally] recently for nurses and doctors and they all said yes but wouldn't know what to do.

Attitudinal shifts are making it challenging, but cannot take all the blame for lack of research uptake

A potential compounder of this is the attitudinal shift of the next generation of potential researchers. Times are changing and so are the behaviours and work cultures of young people who may have previously opted for a career in health research and clinical trials. Interviewees identified that there may be a preference of current younger generations in the health care space to prioritise other things beside research, such as family time, socialisation, and monetary incentives.

Not attracting young academics. GPs trying to get away from a hospital and universities. Have a teaching fellowship at university now, but more desire to do teaching than research.

Harder to get talented young clinicians to get a research career going in a hospital context. Incentives of graduates are orientated to the high-pay areas that are not research. Very hard to find those people who will do PhDs. Even if that does happen, it doesn't always follow through. Today's generation of SMOs have other priorities, academic ambition is not one of them.

Significant barriers exist for those that do want to be involved in clinical trials

For those that do want to be involved in clinical trials there are significant barriers. Most interviewees recognised that their institutions (bar university appointments that have specific research functions) perceived clinical trials as a 'pie in the sky' and an element that would be nice to have but simply is not sustainable with current resource constraints.

Very few post-doc positions, need more of them. HRC used to have many more fellowships and career awards for people to work, which gives people capacity. Thought this was wasteful so stopped – no one has filled the gap. When there are new people coming through, they are given huge teaching commitments and no time for research.

Research is the poor cousin to clinical services for time and commitment. Research can be put back but clinical work can't.

We heard from some interviewees that DHBs often had a negative reaction to health research more broadly because it would create more work for an already stretched workforce.

[Middle management] don't want research to happen because it could mean extra work for the DHB (bad culture).

Others recognised that there is often no clinical time buyout for research. Non-clinical time allocation in a contract is generally eaten up by administration or simply clinical care overrun.

Shortage of time... [some] doctors have some non-clinical time but other health professions don't have this.

Bought out time ... in practice... It is hard to take work away from us without increasing the [staff] numbers. Need to employ more consultants. It [buyout of time] doesn't seem to solve the problem; need more people on the ground. When we job size we need to include the trial and research work.

Overall, the issue of research not being considered a core component of health care in Aotearoa is a driver of many more issues at the system, trial, and individual levels. Issues at these lower levels feedback and may further perpetuate the weak research culture within health care.

Funding, research culture, and workforce capability and capacity have a lot of interdependence

Funding, research culture within health care, and workforce capacity and capability have a lot of interdependence which fundamentally makes a lot of sense. Without funding for research, people will likely be less inclined to partake and only those with extreme drive or persistence will be successful and involved in trials. The opportunity cost for involvement in research is extremely high and a lack of financial compensation for involvement in research perpetuates this.

Lack of funding means self-teaching and taking up more responsibilities than they should

A lack of funding has flow-on effects for workforce capacity and capability. Those who are persistent with research often must muddle through and do not always have the appropriate skillset and resources to reach their full potential.

If it's not formal training though, people just muddle through often.

It was also heard that this is common not only because of staff shortages in some areas, but because of a lack of distinct, dedicated on-the-job training opportunities for researchers.

Clinical trial capability is thin on the ground and some trying to do it without the skills. Risk of doing them badly if we don't have a critical mass of people with [built up] competencies.

A poignant and recurrent example of this is of statisticians assuming the role of data managers and absorbing the responsibilities because there is usually no funding for data managers within clinical trials grants in public good trials.¹ Essentially, they do more work than budgeted for in terms of allocated FTEs and must upskill themselves in data management practice off their own back.

Often must use statisticians as a data manager anyways, because of lack of resources and use of data managers.

[Interviewee] almost ends up becoming the data manager even though that is not his role. Ultimately must do it, because otherwise it impacts in the long run when trying to do the analysis.

If statisticians are undervalued, then the data managers might be even worse off.

In other examples, interviewees expressed that investigators on tight budgets (due to a lack of funding) overstretch themselves across the different responsibilities such as statistics (randomisation) and data management in the early stages of trials (where they may have no expertise). Statisticians and data managers shared that this generally ends badly as the investigators are out of their depth and have poor practice regarding statistical methodology and data management strategy.

Probably comes down to education for people. When you start creating studies, you generally do it on your own without the [funding] support. People get used to doing it all, and not utilising the data management system.

[Statisticians often] get halfway through a project before seeing a protocol.

See a lot of stuff that could have been prevented from happening in the first place – a lot of trials ruined and a lot of issues because of the lack of knowledge about good data governance. Can be uncomfortable and often there is not enough engagement with us as statisticians.

There is a snowball effect of the poor practice at the start of the trial through to the end when statisticians and data managers are called upon for analysis, cleaning of data, and compiling of data.

¹ In commercial pharmaceutical trials it was heard to be slightly different – pharmaceutical companies generally have dedicated teams that provide technical support for clinical trials, and therefore if a statistician was brought in to work on the trial, data management would likely fall outside of their role.

Statisticians and data managers end up doing more work than should otherwise be required because they must try and correct the poor practice from the start.

In some cases, project leads tend to like to spend as little as possible on data management, choosing inadequate tools because they cost a lot less etc. [When there are] funding pressures, data managers go first. Primary investigators and decision makers don't understand the trade-offs about robustness of options.

Situation where you choose a system that is cheaper in terms of money, but then takes way longer in the long-run and becomes more expensive. Yes, get a cheaper system, but must spend more work hours in managing the data and can make it longer in the long term.

People who don't understand how to do trials, going ahead blindly – not seeking the right [statistical] advice in the first place. Trying to do trials that cannot be done within NZ budgets – too ambitious. Often issues because of poor data governance, unsuitable data practices, data that you cannot be certain of the quality. Consequence of the naivety.

In extreme cases, if something such as the randomisation technique is wrong then the entire data output may be invalid. Involvement of statisticians and data managers at an early stage would remedy this issue, however budgets are often considered too tight to do so.

Health economists are also in this same boat with researchers trying to get by without them for as long as possible and include them in the research process at the last minute. This often leaves the health economist unable to contribute in a meaningful way or with a giant workload because the right questions and the right cost data were not collected at the right stages in the design and beginning of the trial.

People coming ad-hoc to health economist to get them to tick the boxes for applications ... [creates] behemoth at the end that doesn't work. Don't want to give a good FTE for them either, just an add on.

Seen as a tick box [requirement for grant approval].

Lack of resource [for us] means having to do things that wouldn't pass muster elsewhere.

'Soft' funding creates low job security, discourages uptake in research positions

The issue of 'soft' funding (salaries that are paid for and determined by research grants) is at the heart of the interplay between funding and workforce capability and capacity. Interviewees expressed that the nature of soft funding and reliance on grants means low job security for people in research positions within both DHBs and universities, and generally low supply of these roles.

Squeeze is everywhere now – feel it too with administrators in the university. Squeezed out of our department and taken the money and centralised – particularly after COVID. Not having discretionary money there to keep people afloat.

Interviewees highlighted that soft funding is no longer easily usable for hiring post-doctorate researchers. As a result, recruitment of young academics in the clinical trials space is difficult.

Gap in the post-doc positions – used to be able to carry people on soft funding, but much harder to do these days. Also not necessarily allowed to do it because of the institution

rules now. Little certainty of a career for young academics starting out now. Has led to difficulty recruiting.

In cases that people do take up 'soft' funded research roles, they are often under resourced and required to do a lot more work than the budget permits. For example, interviewees stated it was not uncommon for statisticians and health economists to have low or severely under-representative FTE allocations in grant proposals, but working much more on the project.

Not much going into the budgets for any kind of data stuff. Hard to get across to the PIs to have a robust data system.

Huge amount of time given up front, expected to take a token FTE, accused of not bringing in enough funding, end up doing way more than the token FTE granted.

[Health economist interviewee] named on 5 HRC things. Every single one of them has been allocated 0.03 FTE – unbelievable.

HRC budget is only so much – if it is a large trial and you add all the investigator salaries and overheads, not a lot left. Sometimes, since biostatistician salary already paid by department, they try to put the FTE to a minimum. Not actually the case, have to be working much more than the minimum FTE.

Another issue highlighted is that soft funding does not allow for capability building because of the short duration of grants and the uncertainty about the future of employment. The lack of longevity of the position may discourage upskilling and training and may also prevent it from occurring organically by forcing people to move around a lot from project to project (without being able to dedicate their time to specialisation).

Fellowships tend to be for researcher in first 10 years not any senior ones in NZ. Nothing after the initial ones and they will go to Oz [Australia].

Challenging to develop consistently funded professional staff, and to have the confidence that you will have their institutional knowledge day in and day out (i.e. don't have to keep getting people in)... hard to continue a research programme with the continual research capacity.

Funding for investigator-led trials does not always make it to the floor where the trials are happening

Some interviewees made it clear that funding for investigator-led trials does not always make it down to the level of staff where the trials are happening. Investigator-led trials are often portrayed as a one-person show which neglects appreciation of the contributions of staff at the ground level involved in the trial, such as nurses administering treatments and care.

Would be better if there was money that came down to the floor not to just the Uni level where they clip the ticket.

Other interviewees built on this, saying the primary-investigator-centric mentality and lack of appreciation and collaboration with other team members does not lead to successful trials. Many agreed the most enjoyable and productive trials occur when there is close collaboration between the entire team and the primary investigator right from trial design through to dissemination.

[Needs to be] movement away from the idea of a lone, key researcher. There is an idea that the PI build their career and take charge – cannot run a CT with one individual. To run a good CT, each member of the team is equally valuable. If you don't have good resources and a good team, you don't have a CT happening.

[Needs to be] housing of statisticians in applied settings (hopefully viewed as important role), but [currently] still seen as second fiddle compared to the PI, even though the trial design and methodology is generally the large chunk of stuff to be done.

New Zealand far too hierarchical in where we think ideas come from, and who we think should be leading the research.

There are some extremely persistent researchers paving their own way, but they are few and far between

One of the key findings from the interviews is there are some extremely persistent researchers that make things happen and bear the weight of Aotearoa's clinical trials landscape on their shoulders, however, these people are few and far between.

A lot of the people who are successful have been involved with clinical trials for a long period of time and have accumulated skills and put in hard work to build systems up around them (often through their own resource) to help orchestrate trials.

Built up a team with time and market, managed to build competency and capability, but degree of fragility because it is project-based money they feed off, rather than the capacity funding which exists in CRIs.

Part of this is also from clinicians networking nationally and internationally, teaching each other, and lifting themselves up together to become more capable in designing and running trials. Over time these researchers have generated a reputation for success that keeps trial activity coming back to Aotearoa.

I accrued my experience and was co-taught. There is not a national resource about how to address a research question and how to design a trial. This is different in the UK where they have a resource to do that. You can go to the networks but they take a lot of money you are funded and add complexity. This problem could be solved if we had a nationally funded resource for a permanent office (doesn't have to be big) with expertise in how to design, set up and run a trial etc. Need to have it to give a standard approach.

The thing with these [successful] people is that they can reach out across medical communities and get primary practitioners and other clinicians referring to them etc. which helps their ability to recruit immensely

These people, however, operate in silos that are not seen widely across Aotearoa.

Some are strong, ANZAC [for example]; incredibly good and lead the world in collaboration clinical trials moving forward. Other ones should strive for this. Made huge difference in clinical practice. Simple but key questions that they have put to the test. Need to do more of this; [however] tends to be silo mentality.

Numerous interviewees identify that current success is often determined by who you know, and what appointment you hold (whether that be medical, academic, or a mixture of both). Collaboration often happens through informal networking and the positions people hold. Without this connection, trial activity would likely be zero.

Cannot easily replicate this [model]. Contingent on this one person who has engineered the role for themselves to do this effectively... relationship that spans academia, institutions that support primary care, and primary care itself.

Some silos of excellence that could benefit from sharing and a bottom-up lifting approach for peer capability and capacity

Further, some interviewees recognise these silos of excellence could benefit from sharing research and undertaking a bottom-up lifting approach to develop peer capability and capacity (which may also encourage people previously outside of health research to undertake clinical trials). Although not necessarily applicable to all groups, some may benefit from pooling of resources across specialities to work on bigger and better trials, rather than compete for smaller grants.

This was highlighted particularly in the context of renal, diabetes, and cardiology clinical trials. Interviewees highlighted that there is a lot of cross-over between these specialities and therefore there is likely benefit in being part of the same network and employing a group approach for applying for research grants and developing research questions to conduct trials at a larger, more effective scale.

Need to do more of this [networking]; tends to be silo mentality in some areas. Diabetes, renal, cardiology etc. ... overlap is so strong and can take it from each specialties endpoint that means less double handling. Look at network with recruitment involving all groups not just one or the other to remove the silo mentality and reduce the competition for limited funding.

In the current scenario, groups such as these likely compete for the same grant funding under the competitive grant scheme and may also try to answer the same or similar questions at a small scale.

Succession is a high-level, system-wide issue that stems from the lower-level issues

Numerous interviewees expressed concern about the succession of Aotearoa's health research workforce because of the perceived increase in barriers to entry over time. It is widely recognised that there are some enthusiastic people who would love to be involved in clinical trials, however, generally lack awareness of the avenues, support, and critical mass.

Chicken and the egg situation currently. Not an easy or short-term solution but need to grow the pipeline of Māori academics.

Don't go into academia for the money, therefore trying to recruit academic clinicians is a challenge generally, beyond just trying to recruit non-clinical researchers within the sciences and health. Another stream – lack of academic clinicians and not really having much of a pathway there unless you know people to get your path in.

[Clinical trials need to be made into] something that is not as scary to the doctors coming through. Still in the too-hard basket. Colleagues will not touch because no exposure. [Need a] mentoring system or some sort of programme – we can buddy up with Liggins or something – spend time there, have it as part of GP training.

At the moment have some internationally recognised key opinion leaders for clinical trials in some areas, where any sponsor desires to work with them because they are well regarded. The difficulty is they are ageing and will want to retire.

Some interviewees recognised that the barriers to doing trials decrease once a position has been established.

Reliant on people having the internal enthusiasm to get going. Once you get going, then it has traction. Many people that probably have interest, but the first few steps are too challenging if you don't have a network or service in your specialty.

Some gaps exist in the workforce entirely

Interviewees made note that in some specialties there are entire gaps with almost no capacity or capability in Aotearoa.

Stats, economics etc. are very fragile, paucity of [data] monitors and [research] coordinators; lack of formal training programmes bringing on experienced workforce.

The second specific example was of capability to deal with Māori data sovereignty and relationships with iwi, Māori stakeholder groups, and whānau. Interviewees shared that often Māori colleagues were given this task on top of their other work responsibilities, even if they had not been training in Māori data sovereignty or had experience in engaging iwi and stakeholder groups.

Struggle to get Māori or Pacific clinical people, the people we do have are pulled in many directions.

Whānau never included within [clinical trials]. Tend to be culturally blind. Never really received written outcomes from the trials.

Most people versed in Māori advisory need to be attracted and recognised in terms of their time [resourcing issue currently].

Don't see the bodies coming through the door, interested in what we are looking at.

Thirdly, we heard that researchers and funders often struggle or fail to find the appropriate ways to engage with and incorporate community oversight and involvement in trial design.

Disconnect between what is important to consumers, and what the sponsors and funders believe it is.

[Consumer involvement in prioritisation is] currently not a well-defined process – various drivers behind it and having no consistency. Different in an actual framework – currently done behind closed doors, decided by people for us as consumers.

Fourthly, we heard from Pacific researchers that people often fail to communicate the importance of clinical trials to Pacific communities, in terms of recruitment and treatment more generally. Pacific communities are often not thought of to be included in clinical trials (particularly by non-Pacific researchers), especially those that are researching big issues for Pacific peoples such as gout, diabetes, and rheumatic fever.

Pacific peoples not traditionally included or even thought of to participate in trials that might have a lot of impact for them (i.e. diabetes). The researchers, majority non-Pacific, do not get the messages out to the Pacific communities, or do not know how, to get their involvement.

Huge disconnect between clinical trials researchers and Pacific communities. Do not engage them. Biggest thing is that we don't have enough Pacific researchers, that would understand and engage with the Pacific community.

Additionally, researchers often do not portray information appropriately to Pacific peoples either about:

- what the purpose of the trial is (i.e. the research question)
- what the trial involves in terms of treatment
- what impacts the findings will have on people, particularly Pacific communities and families.

Once you explain a trial to the Pacific community, they see the relevance of participating in a trial and the relevance of contributing to the greater good. With that comes the caveat that they always want to know the result – will you tell us whether the medication will be useful? Important that they can see the results tangibly. Explained well, benefits portrayed, information dissemination good to ensure participation.

People lack (or are unaware of) best practice guidance

For a lot of people, examples and resources are important for providing a reference of what success looks like and mapping the path to get there. Interviewees told us that they have generally found it hard to find consistent guidance and resources for numerous different aspects of clinical trials.

Useful to get exemplars that are working well – joined up view of the puzzle pieces. Otherwise get particular expertise and results and can get defragmentation.

We don't have a statistician [at the DHB], so where and how do we access this?

Find people asking for our [biostatistical] help for trials and find they don't have the support around them.

Two of the main areas that people struggle to find guidance with are Māori and Pacific community engagement (outside of HRC research guidelines), and appropriate data and statistical systems to use, how to use them, and what best practice is elsewhere.

Don't have a mechanism for it [Māori and Pacific engagement and guidance] and don't understand it fully, a real issue and there needs to be workforce development.

Large element of reinventing the wheel for data systems [and statistics]. Can refer people to good randomisation processes, data capture tools, but in the end, generally having to do or a whole lot of rediscovery [for them] about how to do these things.

In addition to this, there are sometimes conflicting examples nationally and internationally that can compound issues with understanding best practice and the appropriate processes to follow throughout the trial and subsequent care.

Variability in local processes ... often leads us in big loops that take a long time.

Nationally inconsistent approaches with research and even more so the findings of the research. Then what? Research takes place from special interest areas, but there is no consistency about how it is then rolled out (varies considerably from DHB to DHB). Variability in care, and fear of missing out on the best care [as a patient].

People are not aware of training opportunities, if they exist in the first place

It is apparent that in a lot of roles within the wider clinical trials system, people are either unaware of training opportunities (i.e. not well documented), or they do not exist. At the highest level, there is no specific pathway for clinical training in Aotearoa with a focus on research and trial capability. Some interviewees felt people are not being shaped or well-equipped by educational institutes to undertake clinical research.

No clinical research training pathway, no recognition as a career effectively. No established research career within the colleges – don't allow that.

Health often not seen to be a place to develop your career, let alone [for] innovation. Hard to find people to come aboard because they are unaware of it. Never been exposed to the potential for a career in health.

Data managers highlighted that there is generally no formal pathway to become a data manager for health research (much unlike other professions that have applied courses such as finance). The skillsets learned in other courses are not always necessarily interchangeable, especially since clinical knowledge and understanding is essential for effective data management in clinical trials.

Never really had data management brought into clinical research training or university training. People come to it from such different mechanisms, informal networks etc. ... Working as a clinician also helps. Having a health background likely helps with the inputs and understanding the relationships and dealing with medical information – understanding the context of clinical data and the interests in outcome measures.

People fall into the roles ad-hoc. Hard when working in a clinical environment to get someone with clinical understanding and the technical expertise for the database management. Few and far between.

Not like statisticians where you must generally have Masters, PhD etc. ... people find their way in without any specific plan to do it. Find themselves working in data, and then decide to go specialise there.

As for the researchers, they seem to have a clearer guideline about progression up the scales. Those not on the scale, much more ad-hoc. There is, however, progression opportunities. Just nothing concrete around what it is.

Health economists that were interviewed also recognised the distinct lack of formal training pathways for health economics and cost analysis for clinical trials. Courses that do exist for health economics (especially taught for Master of Public Health courses) are often fragmented which creates large jumps

in complexity (i.e. from undergraduate content to postgraduate complex modelling) that can be off-putting as well as ill-preparing.

[A] need for a master's degree in health economics. At this point, cannot improve things by pump priming in terms of getting people to do things.

Students going through from Master of Public Health level [learning] about the broad questions, into decision analytic modelling. Too big a jump. Been this way for years and years.

Needs to be a better blend of economics and public health – need to fund scholarships to get the workforce up and running.

Data managers identified that training opportunities generally do not exist for programmes that are commonly and widely used, such as REDcap and that there is largely fragmented and unsupported education about data systems.

Training could do a bit better, especially in REDCap. There is a REDCap support group within the University because there is no formal training.

Never really had data management brought into clinical research training or university training.

Statisticians highlighted a lack of training and educational opportunities which often leave Aotearoa behind the rest of the world in terms of methodological changes and new, iterative best practice procedures.

[Lack] access to good methodological help to develop new techniques – isolated in NZ. Occasionally can engage with others, but very rare. Haven't had much time to develop anything new – become technicians.

Training-wise, given limited opportunities to train in-depth in the statistician level, do it at the highest level to participate overseas. However, don't often have the resource or the ability.

Always a bit shocked by how limited peoples' ability is for writing script in a stats package in a repeatable way. Area where there is a relatively easy whim in trying to upskill and get people to operate in better ways.

Most said that going to training conferences and other educational events would generally require individual investment, or some ad-hoc financial arrangement. In a specific example, one statistician said their department would send one person across to Australia to attend a conference a year (rotating each year). That person would then be tasked with teaching everyone else when back.

Conferences where you can upskill, opportunity to present applied findings is hard and might not be of interest. Occasional opportunity to innovate methodologically in those settings. Access sometimes approved on general networking reasons.

Groups will fund people to do them in Australia, but they are so expensive. [They] would come back and train the people left behind but doesn't work that well. Better if more people can go along and get more information.

Been to a few conferences – not really a regular or published expectation or guidance around what to expect in this way. When been to conferences, [had to] put together a proposal, benefits, costs, etc.

Numerous suggestions by interviewees to build capacity and capability

Interviews highlighted a myriad of avenues that could be pursued and may result in an increase in workforce capability, capacity, and engagement in clinical research and more specifically clinical trials.

Making research a core component of health care

The most consistent recommendation from interviewees regarded making research a core component of health care through numerous mechanisms. To entrench research within health care, interviewees suggested three main actions.

Firstly, the introduction of research performance measures for organisations receiving Government funding for health care. To qualify for the full amount of funding, organisations would have to dedicate a certain amount of time and resource to research and clinical trials, and possible transfer patients from standard health care into clinical trials. This could be done on a quantity or quality basis.

Ensure research becomes equivalent to standard to care in primary health organisations, obliged to offer research as a treatment option [and] need a KPI or measure.

Some kind of performance measures related to research at the top level as a measurement for service providers, could improve the uptake of research.

Clinical research outcomes as a KPI. Feels like right now DHBs tolerate research rather than encourage it.

[E.g. require] 10% of patients enrolled in studies [as part of health care].

Secondly, making research an attractive pathway for medical students coming into the industry by:

- Making a research project a requirement for medical degrees. This may lower barriers into medical research later in life and give students an insight into a potential career pathway.

Research tracks for professionals. About enriching. E.g. in Fiji, keep them there by doing research and adds to quality of profession and satisfaction.

Registrars now have to do scholarly project for their college (Australasian) – of the order to get to a low-middle order journal. Not creating people who suddenly realise they want to do research.

Must start at the level of med schools, and then pick it up and run with it. Having the funding to have RMOs in research etc. would be great, might whet their appetite for research.

- Increase/change allocation of funding to provide more workforce development opportunities and academic roles. Currently, those in academic research roles may not be earning as much as elsewhere. More research positions, or a greater allocation of current funding to these positions may encourage uptake.

More training opportunities more useful at a higher level. What you can get from 1-day course compared to reading things around is good, having access to the experts all in one.

Want to get scientists or clinicians early on and give them the chance and mentoring to get involved in research. Could be that access to funds, mentors, equipment, would give a bigger capable cohort of doing clinical trials.

- Making GCP (good clinical practice) courses part of the norm so medical students are prepared when entering the workforce. This may make barriers to entry into clinical trials lower and could enable easier entry into pharmaceutical trials (which subsequent public good trials could piggyback off).

GCP training are must haves and should be standard. We are doing this.

GCP is good [development opportunity] for the formal, regulatory requirements [of trials]. If its not formal training though, people just muddle through often.

- Consistency in travelling grants for students to get expertise from overseas medical schools and facilities and come back knowledgeable.

Travelling grants to allow people to go overseas and undertake degrees etc. Expectation is that it is a skillset that isn't present in New Zealand and will bring back.

Providing resource or guidance to lower the barriers to successful trials

It became apparent that often the first few steps of the trial can be the biggest hurdle, especially for small organisations or people who have not done clinical trials before. Interviewees suggested there needs to be greater provision of resource or guidance to lower the barriers to acquiring grants successfully and conducting successful trials. This includes:

- Guidance on funding applications to receive research grants, the required steps to take, and how to string it all together. One interviewee stated it would be useful if government agencies could provide some directive assistance as well.

Helping people seek funding would be good. Often a barrier; initiating grants and building up the capability of this at a service and individual level is quite challenging.

Ability for government agencies to write letters of support for research. They are currently not allowed to. Disparity between what funders want and what government need.

- Check sheets of the different elements to include in funding applications, protocols, trial design, and co-design with Māori and Pacific.

More advice about what [resource and support for Māori and Pacific engagement] is available will be helpful.

Need a template on how to do it ... prioritisation, [trial] design, how to get it funded, how to conduct, analyse and implement findings.

General principles when dealing with Maori participants (organisations, researchers, individuals as participants etc.)

Need Pacific-specific advice. Wrapping any project we are involved in with a Pacific community panel – have context with their various groups and communities, makes a massive difference.

- Worked examples of successful trials (from design phase, to funding, through to dissemination, etc.) and 'best practice' scenarios so people can copy, replicate, and tweak to their own setting.

[Need] expertise to develop robust protocols so we know what best practice is e.g. NHRMC have this.

Useful to get exemplars that are working well – joined up view of the puzzle pieces. Otherwise get particular expertise and results and can get defragmentation.

- Information, advice, and support for statistical and data management requirements for running a clinical trial so that investigators do not get in over their head at an early stage, and those doing data management and statistical analysis are aware of what methods and data forms to use.

Most [researchers] can't support their own so a common resource would help this. Only bigger places have them. Data management pool is very transient. We don't grow our own well [in New Zealand].

Guidance from some governance level around data standards, working towards nationally consistent datasets.

Secondly, interviewees suggested greater interconnectedness with national and international trial networks, partners, and systems could lower the barriers to involvement with clinical trials since single sites within Aotearoa are largely too small to compete for trials on a domestic and international scale. Heightened focus on collaboration and networking domestically and internationally may:

- Inform members of up-to-date best practice methods and research questions at the frontier of specialist fields.

University groups [are] quite isolated – can be data manager for one group, but don't really mix a lot with other groups. Need more networking to see what is being used, what is good, what isn't. Could easily get behind on tech and practice because they don't have mixing with others or have the training or anything.

National consortium/network to consult with – having a buddy or knowledgeable people to turn to for help.

- Lower barriers to collaboration within Aotearoa and with the world. Effectively, an active presence in a trial network or system could encourage more involvement from sites in Aotearoa.

A partnership model e.g. primary care and a specialty group behind you is useful. Gave more clout to the project ... allow more areas to participate.

Primary care practice group that works together – would be beneficial in getting things up and running. Some things have happened in little ways, but nothing significant and coordinated.

Access to forums and help from appropriate places. Need backing from appropriate agencies to make change happen.

- Provide greater access to resources, including the benefits of networking with skilled colleagues. These opportunities to network may also foster greater collaboration and involvement in clinical trials.

Join forces within the community (GP, pharma, physio etc.) to grow capacity and network.

For example, San Fran group, [with] rare cancer. Marketplace for high-risk cases in the pharma market is ~1500 kids a year. They ran a trial and it was successful – the cost of the medication is approx. \$400k a child. Because of the connections they have through the network, the delivery is almost \$0. Connection is absolutely pivotal to the change in survival for this disease. Funding for clinical research associates, and networks has meant they have been able to offer the clinical trials to the children. Benefits for children that flow on.

Additionally, interviewees suggested there should be explicit requirements for successful research proposals to involve multiple groups earlier in the process of trials, such as statisticians, health economists, consumer groups, Māori, Pacific, and other minority or typically underrepresented groups.

Application for funding – [needs to be] minimum requirement for community person involved; if not investigator, advisor, or something in the beginning to decide what is important for the consumers.

Need some infrastructure to make sure that the perspectives are heard and brought through into the clinical trial design. Instead of top-down HRC priorities, build up from community expectations and needs.

More conversation [in grants] about the requirements for health economics to be successful – [show the required] outcome measures, cost measures, etc.

Knowledge translation and translational research is often neglected

Interviewees raised numerous issues surrounding the translation of knowledge from clinical trials, right from researcher-to-researcher research, data, and findings discovery through to embedding new practices in day-to-day health care.

It was heard immediately that translation of findings and knowledge from clinical trials (and in wider health care and research) is generally hard and very variable in its effectiveness across Aotearoa. There are some good examples of inter-discipline groups that translate knowledge from researcher to researcher, but not necessarily into health care practice.

Research grant mechanisms largely dictate the ability to translate findings into health care

The most common issue raised was that translation of findings into health care is greatly restricted by the grant system since there is hardly ever any resource available for post-trial follow up and implementation of findings. The grant system drives researchers to where the money is, which is usually in doing a new trial and not necessarily where the meaningful results are.

Driven by the grant system, don't have the resources for follow ups. grant system drives you to the money and not necessarily where the meaningfulness is. Cannot see it right through to the next stage often, can lead to a lot of competition between institutions.

We follow the money and move between topics as political parties change e.g. from prevention to treatment.

Additionally, there are usually no requirements when applying for a grant that ensure there is some sort of post-trial follow up or application of the findings to health care.

Translation is where it is sometimes the weakest. Once published, not much follow up. Takes 17 years on average for research to change clinical practice (anecdote) – interesting because probably true. Reasons why? For patient safety, clinicians tend to stick to what they know until they get to see that it is safe. Clinical translation may be slow and for the wrong reasons. Stick with what they have always done. Need to move the evidence from journals to the practice.

Health economics and cost analysis also falls into this basket. There is usually little health economic assessment or cost analysis done for clinical trials and it is often an afterthought which makes it largely ineffective. Evaluating method efficiencies and cost-effectiveness likely speeds up the translation of findings into clinical practice if efficiency gains or cost savings can be shown.

How will you show your thing is better? Need the right outcome and cost data and have to show it is better than the other approaches. Will not be able to take it any further if you do not provide that evidence. Without it, it will not fly especially with competitive medicines.

E.g. intervention that increases access to care. Don't just ask what A vs B is and does A beat out B – can talk about the value of being able to access care. B may be not as good

as A, but perhaps A is extremely expensive, and the marginal difference isn't worth the investment. Need to be able to frame things widely and motivate things around a whole bunch of other questions that a statistician just will not be able to.

There is a gap between research coming out of universities and CREs, lacking pragmatism, innovation, and development of new translation methods

There is not much research well placed between that bridges the gap between universities and CREs in terms of being pragmatic, innovative, and generally applicable to large population groups. Interviewees saw this largely as a problem of translation and that research of innovation and development of new translation methods for existing problems was not consistent.

University research being generated through post-grad theses etc. – quite a difference between the university research and crown entity research. Not a lot well placed in between. Not seeing the innovative stuff elsewhere. May not be specific to New Zealand, but there is a translation problem.

Other interviewees expressed that there is not enough focus on trials with pragmatic end points and applications to society, and that there is typically a greater focus on novel small sample trials that may be cheaper to run but are harder to translate into everyday health care.

[Need] more pragmatic studies ... find the 'simple, easy' results that will be beneficial for a wide range of people.

Pragmatic trials may be more costly, more involved, but may be richer in their applicability.

One interviewee mentioned bioengineering specifically, where university research agendas usually pushed PhD students to look for niche findings rather than practicalities useful in everyday life.

In [bio]engineering section, maybe Auckland better than elsewhere, more focus on clever ideas than practicalities – reflects university sector for pumping out PhD students for niche findings rather than translational studies and implementations.

This may come back to the drivers and prioritisation processes of universities and how they decide what research gets funded and what students are led toward.

Translational research is expensive and therefore most struggle with it

Overall, translational research is expensive and therefore any research institution that is resource constrained (i.e. most) likely struggles with it. The only exception to this is usually in the commercial informational technology space where innovation can be low cost and happen organically.

Anywhere resource constrained struggles with translation because it is generally quite expensive unless it is almost organically occurring in the commercial IT space.

Some interviewees claimed there is generally great buy-in from clinicians with medical technology interventions and devices, but ethics surrounding multi-site trials and non-traditional clinical outcomes makes it hard to implement.

Great buy-in from clinicians and want to work closely with them to refine the design to assure that the usability is correct and no unanticipated safety issues to build confidence before going to market.

Often struggle when new equipment is being developed. Iterative changes, not necessarily completely novel. E.g. modification to existing therapy (materials, configuration, retention etc. might be different). Model of research that doesn't fit any particular box, quite different to how pharma trials are run, no major clinical endpoint. Ethics committees often do not understand the approach and why they want to do things the way they do.

Additionally, they identified that it is hard to put medical technology interventions and devices into small hospitals because the resources required to set up administration in those hospitals is disproportionately higher than the low number of patients likely to be gained.

Burden of the set up and administration, wouldn't be worth for the number of patients they would bring to the study. Must train and get people up to speed – need strong medical champion, nursing champion, and someone other than clinician + finance to be able to help you. Otherwise, will be exchange emails for 2 years and nothing will happen. Not part of their core business – must really want to be part of it to make it work. Otherwise just not possible.

In terms of drugs, interviewees recognised translation in Aotearoa is hard because it is too small of a market, and the funding market is restrictive. The costs are generally large per patient added to the trial. PHARMAC and ethical upkeep of standard of care also pose as barriers.

Drugs is hard for translation in NZ as it is too small to get a group to get a drug from the chemist's bench to an approve drug for patient. We won't be able to do this.

To lower costs, others suggested that access to resources and collaboration with IT departments could make it easier to innovate and translate, especially with the ever-increasing range of tools and applications.

Could innovate within DHB if we had access to resources from the IT department. Other DHBs have very innovative clinicians but using tools they have available. If there was some way to access it (maybe nationally) then could probably develop good things quite quickly. Having within-DHB access to system architects, having things embedded into the IT business-as-usual that is much more than just infrastructure within clinical trials unit.

Generally, there is no traditional role for facilitation of translational science in clinical academia

Generally, there is no traditional role for facilitation of translational science in clinical academia, and no one pushing things along to get them adopted in everyday health care. There are few positions currently occupied in clinical academia that are involved in early-stage development of ideas to ensure

they are clinically significant, useful, and effective which can then be used in day-to-day care to improve outcomes.

Feel my role is important, but not traditional clinical academic and couldn't come up with a dual appointment – had to leave university and get seconded back. Need more of these [roles to act as] the liaison for the good ideas coming up at universities and between clinicians.

Many interviewees identified that it can be hard to bridge the gap between clinicians at the DHBs and academics with bright ideas at universities, often with a mismatch of needs and ideas. There needs to be a middle person facilitating and matching ideas and needs to ensure the burning questions are being answered.

Start-ups finding it hard to get in DHBs to work with them – no one front door. Need a front door or some sort of centralised, visible front door for people to go through. Not being able to find the way in for companies and researchers. Always must reach out to people you know – reliant on the connections you have.

Really smart people doing innovative things across medicine in Dunedin. Yet actually, these two parts of the building attached to each other are not well connected (i.e. academic office and the hospital).

To help this, interviewees suggested greater access to forums of discussion and networking to be able to find out:

- Greatest need(s) in day-to-day care
- Research questions that come from the greatest need(s)
- Solutions to answer these questions and improve outcomes.