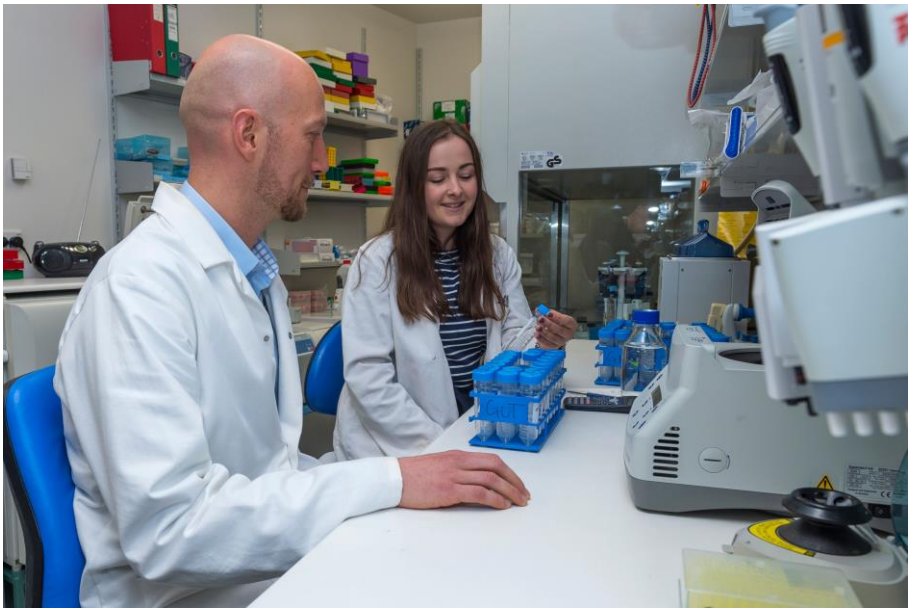
New Zealanders for
HEALTH RESEARCH

Ngā Tāngata o Aotearoa
mō te Rangahau Hauora

Clinical Trials in New Zealand: a discussion paper



March 2019

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Cover photo: Malaghan Institute of Medical Research translational immunology researchers Olivier Gasser and Anna Mooney

Executive Summary

This paper outlines government initiatives to support clinical trials in New Zealand, since and including the 2011 Health Committee recommendations, together with analyses of data available from the US and ANZCTR registers and the HDEC database. It presents the following imperatives for further action:

- Establishment of a national framework for clinical trial research at district health boards, PHOs and other publicly funded health service entities
- Setting of health research/clinical trials specific investment benchmarks and targets
- Development of clinical trials investment strategies which will enable New Zealand to be competitive with Australia (and other countries) as a place to conduct clinical trials
- Establishment of targets and development of strategies which will result in public health providers, including DHBs, attracting increased industry investment in clinical trials, especially drug trials
- Funding of district health boards and other publicly funded health service providers to undertake clinical research as a front-line activity
- Establishment and maintenance of a single accessible register of clinical trials in New Zealand, with sufficient utility, including fields, to enable key elements of clinical trials trends to be reliably analysed and monitored
- Promotion of participation in clinical trials through public and physician awareness raising strategies

Introduction

New Zealanders for Health Research was established in November 2015 to promote and advocate for increased investment in health research from government, philanthropy and industry. A significant component of health research comprises clinical trials which seek to identify the effectiveness, efficacy and safety of potential new therapies and interventions, and which have the potential to produce both improved health outcomes for New Zealanders and economic benefits for the New Zealand economy.

The most recent comprehensive and systematic review of clinical trials in New Zealand was undertaken by Parliament's Health Select Committee which released its report, including 54 recommendations in 2011.

The purpose of this discussion paper is to:

- Review the extent to which the Select Committee's recommendations have been implemented
- Review other government and non-government initiatives with potential to impact on investment in clinical trials
- Quantify trends in investment in clinical trials
- Identify options for lifting investment in clinical trials
- Be a background document to inform discussion and debate at NZHR's "Health and Prosperity through Clinical Trials" 22nd March 2019 workshop.

Health Committee 2011 Clinical Trials Review Report

In June 2011 the Health Committee presented its report, comprising 54 recommendations, on its inquiry into improving New Zealand's environment to support innovation through clinical trials[1]. The Committee instigated the inquiry because of concerns that New Zealand had lost its advantage as a good place to carry out clinical trials. Most submissions received backed up this view and called for improvement.

In September 2011 the government published its response[2] which, with 13 exceptions, either specifically supported the recommendations or indicated that implementation work was already underway.

Table 1 below presents the Health Committee recommendations which are most relevant to NZHR's vision of improved health and prosperity of New Zealanders through health research, and our goal to make health research a higher priority, attracting greater investment from government, industry and philanthropic organisations. It includes the government's responses, and NZHR's assessment of progress over the subsequent seven years.

Table 1: Progress in implementing selected Health Committee clinical trials recommendations

Committee recommendation	Government response	Assessment of progress	Comment
Establish a strong collaborative framework between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise to coordinate and promote as efficiently as possible clinical trial activity in New Zealand.	Broadly supported	Patchy	Some initial progress, which appears to have lost momentum. Progress revived during 2018 as MBIE, MoH and HRC have collaborated in the implementation of the Health Research Strategy. New Zealand Trade and Enterprise apparently no longer a key player
Embed a culture that values research in the New Zealand public health system, by forming a national health research action plan to foster innovation and commercialisation.	Supported	Slow	New Zealand Health Research Strategy produced in 2017. Implementation has been initiated but has not yet progressed sufficiently such that there is embedded a culture that values research in the New Zealand public health system.

[1] https://www.parliament.nz/resource/en-nz/49DBSCH_SCR5154_1/19f143ece9bbafc1f5970397e5d92a582e003faa
[2] https://www.parliament.nz/resource/en-NZ/49DBHOH_PAP21990_1/087b78a44dd4f336f886bf49b5087569a30514e2

Committee recommendation	Government response	Assessment of progress	Comment
Establish a national framework for clinical trial research at district health boards	Provisionally supported	No progress.	The government response suggested this could a function of the DHB Research Fund Governance Group and/or the National Health Innovation Hub. The former group appears to no longer exist, and while the Hub has been established the establishment of a clinical trials framework is not part of its brief.[3]
Ensure excellent scientific infrastructure to run clinical trials, which is regarded as a core part of New Zealand's basic infrastructure.	Supported	Adequate	Under development as part of the role of the Chief Science Advisor
Establish a long-term objective of bringing New Zealand's public and private investment in research and development up to international benchmarks (including research and development relating to clinical trials when benchmarks are available)	Not supported	Limited	Aspirational 2% R&D investment target adopted in 2018 by the government. However this falls short of comparable international benchmarks (ie 2.4% to 3%), and there's been no attempt to set specific health research/clinical trials benchmarks.
Assess the Australian Government's Clinical Trials Action Group's report "*Clinically competitive: boosting the business of clinical trials in Australia*" urgently, with a view to ensuring that the New Zealand systems are at least as efficient and effective as the Australian systems, if not more so.	Supported	No evidence of progress.	Maintaining competitiveness with Australia identified as a key issue by NZHR's August 2017 CT workshop participants, and analysis of ANZCTR data suggests NZ is losing ground.

[3] The Hub is a partnership between the Auckland, Canterbury and Counties Manukau DHBs, supported by the Ministry of Business, Innovation and Employment. http://innovation.health.nz/

Committee recommendation	Government response	Assessment of progress	Comment
The Ministry of Health, the Ministry of Science and Innovation, and the Ministry of Economic Development develop a model to establish an innovation fund for co-sponsoring with pharmaceutical companies, specific clinical trials involved in research aimed at health issues specific to New Zealand's population	Not supported	Not progressed.	
District health boards be funded to undertake clinical research as a front-line activity	Not supported	Not yet progressed	Provided for in the Health Research Strategy.
Improve Health and Disability Ethics Committees' configuration, performance and processes.	Supported	Substantially progressed.	Realised through continuing process improvement and the 2018 NEAC review of health research standards.

Other initiatives with potential to impact on investment in clinical trials

Health Research Strategy[4]

Health Research Strategy actions, which, if implemented, could impact positively on investment in clinical trials are presented in Table 2.

Table 2: Health Research Strategy actions with potential to impact positively on investment in clinical trials

Action	Comment	Lead agency
Develop and sustain a strong health research workforce	Will contribute to the creation of workforce capacity and capability required for clinical trials growth	HRC
Strengthen health sector participation in research and innovation	Will create an expectation that DHBs, PHOs and other publicly funded health agencies	MoH

[4] New Zealand Health Research Strategy 2017 – 2027. June 2017. Ministry of Health and MBIE. https://www.health.govt.nz/system/files/documents/publications/nz-health-research-strategy-jun17.pdf

Action	Comment	Lead agency
Strengthen the clinical research environment and health services research	will participate in health research, including clinical trials	
Enable and embed translation across the health sector	Increased confidence that results will be translated into practice may assist in incentivising investment in clinical trials	
Support transformative and innovative ideas	Increased confidence that innovative ideas will be supported may assist in incentivising investment in clinical trials	MBIE
Create more industry partnerships	May incentivise industry investment in clinical trials	
Strengthen platforms for commercialising innovations		

R&D Investment strategy

In April 2018 MBIE released a discussion paper on a research and development tax incentive for New Zealand[5], and, following submissions, released its implementation proposals in September 2018.[6]

A summary of NZHR's submission (which focused specifically on health research and clinical trials), together with the final decisions on the incentive scheme are presented in Table 3.

Table 3: NZHR's R&D tax incentive recommendations compared with the government's final announcements

NZHR submission	Government decision	Implications for clinical trials
The 10 year R&D expenditure aspiration be set at 3.3% of GDP	Retained at 2%	NZ will be less than optimally competitive as a place to conduct clinical trials
The tax incentive be set at 35% of eligible expenditure	Increased from 12.5% to 15%	As above. Also, 15% insufficient to overcome systemic disincentives to investing in clinical trials.

[5] Fuelling Innovation to Transform Our Economy. MBIE. April 2018. https://www.mbie.govt.nz/dmsdocument/3104-fuelling-innovation-to-transform-our-economy-discussion-paper-pdf

[6] https://www.mbie.govt.nz/assets/f343ac9764/cabinet-paper-rd-tax-incentive-for-implementation.pdf and https://www.mbie.govt.nz/assets/9905654fcb/r-and-d-tax-incentive-summary-flyer.pdf

NZHR submission	Government decision	Implications for clinical trials
Non-tax paying entities which conduct R&D be as equally incentivised as businesses	All businesses, regardless of legal structure, will be eligible to claim the Tax Incentive. Industry research cooperatives (including levy bodies) will be eligible for the scheme. State Owned Enterprises and Mixed Ownership Model companies will be eligible. CRIs, DHBs, and tertiary education organisations, and majority owned subsidiaries will be ineligible.	Lost opportunity to incentivise public health providers to invest in clinical trials
Small start-up companies be eligible for the incentive from the scheme's commencement	A minimum threshold for the scheme will be set at $50,000 a year (reduced from the proposed $100,000)	Positive.
The R&D tax credit be targeted to government priority areas	Targeting not provided for	Lost opportunity to maximise health gains offered through investment in clinical trials
Eligibility include a requirement that R&D activity be founded on robust research methodology	Not specifically supported. The requirement to use scientific methods has been replaced with a requirement to use a systematic approach.	Lower return on clinical trials based R&D investment as a result of a higher methodological standards.

NEAC Review of Health Research Standards[7]

NZHR supported most of the NEAC proposals insofar as they supported undertaking of health research, including clinical trials, that would give participants, sponsors and investors high levels of confidence that research in New Zealand is carried out in accordance with high ethical standards.

However, we believed that proposals relating to provision of third party insurance could act as a disincentive to participation, and proposed that if participants were to suffer harm as a result of their participation they should be covered by ACC.

The outcomes from the NEAC consultation process will be presented at NZHR's "Health and Prosperity through Clinical Trials" 22nd March 2019 workshop.

[7] https://neac.health.govt.nz/system/files/documents/publications/draft-national-ethical-standards-health-disability-research-consultation-jul18-v2.pdf

Therapeutic Products Regulatory Regime Review

The current and previous governments have for some time been working on a new and comprehensive regime to regulate therapeutic products in New Zealand, which will replace the Medicines Act 1981 and its Regulations.

Draft legislation is now available for public consultation and NZHR will be analysing and presenting a submission on its implications for health research.

Under the new scheme, conducting a clinical trial of a therapeutic product would be a controlled activity requiring an authorisation. It is intended that the approval would take the form of a licence that could authorise the supply of the product(s) being trialled to the specified clinical trial site(s) as well as the trial itself.

This means that for the first time in New Zealand, medical device and cell and tissue researchers will work within a regulated trial environment, in contrast to the current scheme, which requires only an ethics approval. For pharmaceutical researchers, it would mean that all clinical trials of a medicine would require approval whereas the current legislation requires approval only for trials of unapproved medicines.

Proposals for clinical trials are presented on page 89 of the discussion document[8], and key points summarised in Table 4 below.

Table 4: Therapeutic products regulatory regime clinical trials proposals

Current	Proposed
Conducting a clinical trial of a therapeutic product not necessarily a controlled activity requiring an authorisation.	Conducting a clinical trial of a therapeutic product would be a controlled activity requiring an authorisation. It is intended that the approval would take the form of a licence that could authorise the supply of the product(s) being trialled to the specified clinical trial site(s) as well as the trial itself.
Medical device and cell and tissue trials require an ethics approval only.	Medical device and cell and tissue researchers will work within a regulated trial environment.
Clinical trials of a medicine require approval for trials of unapproved medicines only.	All clinical trials of a medicine would require approval.
	The new scheme would take a risk-based approach to licensing so that greater scrutiny would be given to applications to trial novel products being used for the first time in humans and high-risk products, than applications for trials researching new uses for approved products or comparing approved products.

[8] https://www.health.govt.nz/system/files/documents/publications/therapeutic-products-regulatory-scheme-consultation-document_dec18.docx

Although ethics approval for clinical trials is established practice it is not specifically mandated legally.	Ethics approval would be legally required for authorised trials unless an ethics approval body certifies that ethics approval is not required.
No single accessible register of clinical trials in New Zealand.	The regulator would be required to maintain a publicly accessible register of licences. This system would therefore provide a comprehensive record of all clinical trials conducted in New Zealand.

Submissions on the proposed regime close on Thursday 18th April. NZHR will be consulting with members and stakeholders through NZHR newsletters, and at the "Health and Prosperity through Clinical Trials" workshop on 22nd March 2019. Comments to ceo@nz4healthresearch.org.nz are welcome at any time from now on.

NZHR Workshops

NZHR's August 2017 clinical trials workshop identified the following as priorities for further action and work:

- public awareness campaign to promote participation in clinical trials
- mandating publicly funded health service provider commitment to health research and clinical trials
- publicly funded health service provider workforce development to create research capacity
- clinician discussion about clinical trials being a routine aspect of patient care
- ACC coverage to be extended to harm resulting from clinical trials

The "Health and Prosperity through Clinical Trials" workshop on 22nd March 2019 will create an opportunity to review progress in addressing these priorities, together with the extent to which they and other issues identified in this paper continue to be relevant and important.

Clinical trials trends New Zealand

The purpose of this section is to identify trends in the undertaking of clinical trials in New Zealand, using ethics committee data as supplied by the Ministry of Health, data available from ANZCTR's report on the clinical trials landscape in New Zealand 2006–2015[9], and NZHR's own analysis of the ANZ, US and EU clinical trials registry data.

It should be noted that:

1. Neither the ANZCTR nor the HDEC database capture the total number of clinical trials, and there is currently no single comprehensive source of data. Although the HDEC data includes all clinical trials that have received New Zealand ethics committee approval, it only goes back as far as 2013 (the first full year), and the data does not include any trials that do not fall within HDEC's defined scope as per

[9] The clinical trials landscape in New Zealand 2006–2015. ANZCTR. 2018. http://www.anzctr.org.au/docs/NZ_Report_2006-2015

the standard operating procedure[10]. However, all clinical trials which have received ethics committee approval are required to be registered with a WHO primary registry.

2. In all cases the HDEC and NZHR analysis figures for 2018 are actual (not projected) figures.

3. Some HDEC data is inflated due to invalid and withdrawn applications being included as well as provisional approvals sometimes appearing as a double up. In an attempt to address this numbers of intervention studies only which have received HDEC approval are presented as subsets of the overall data.

4. All figures come with a margin of error due to being reliant upon how users completed the register fields or ethics applications submission. Particularly difficult for the HDEC database is the sponsor as this is sometimes left blank or marked as "collaborative" (which could, for example, indicate pharmaceutical partnership with a University, DHB etc.

5. 2018 data is or may be incomplete as some ethics applications are still 'live' and awaiting a final decision so have been filtered out. Similarly, there may still be some 2018 trials which are yet to be registered on the US and ANZCTR registers.

6. The ANZCTR report captures all clinical trials registered on the ANZ and US registers (clinical trials.gov) up until 2015, including some trials which have not been given ethics approval, but does not include trials registered on other primary WHO registries. Indeed, around 18 per cent of all registered studies recruiting in New Zealand between 2006 and 2015 are registered on other WHO primary registries.[11]

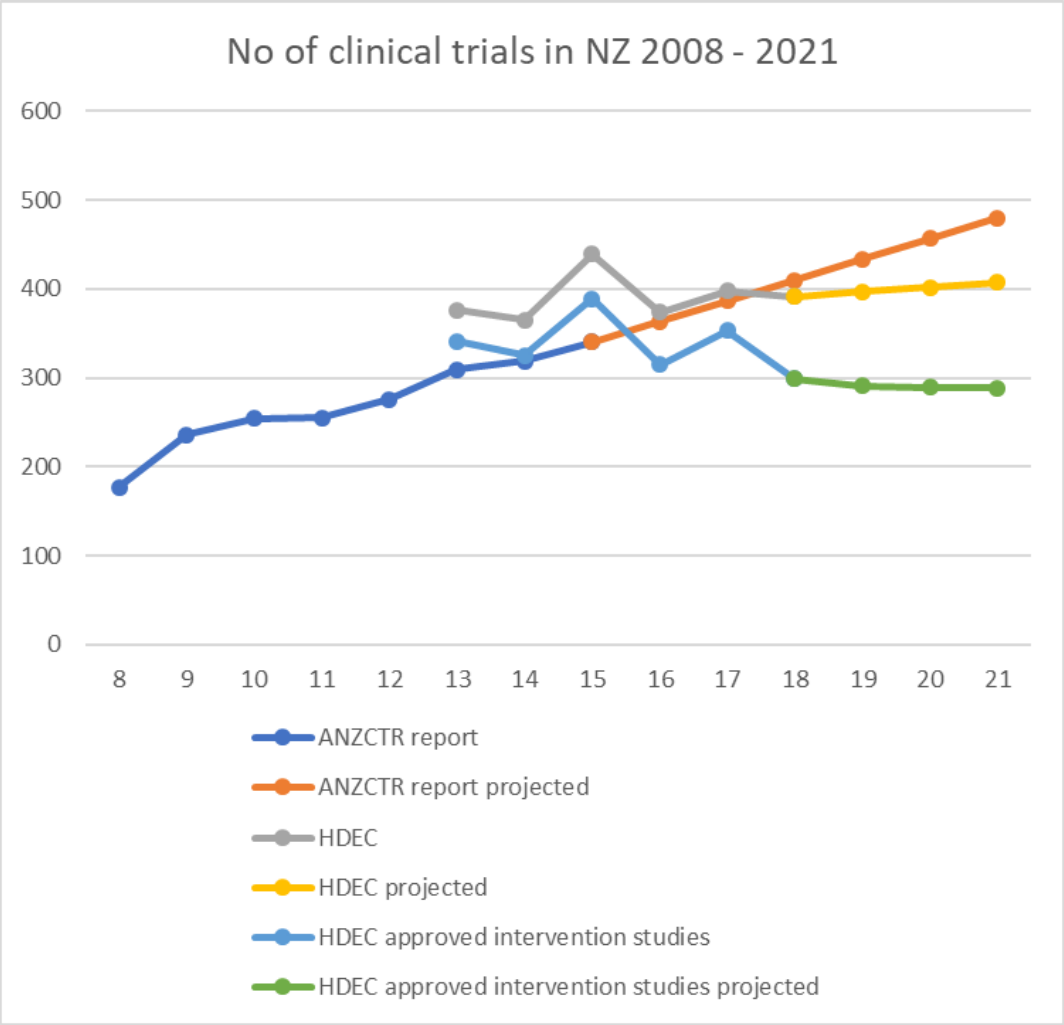
7. While NZHR's own analysis of the ANZ and US CTR's has used its best endeavours to capture all available New Zealand clinical data, this can not be guaranteed, and NZHR's analysis may underrepresent the actual figures. However this paper assumes that any trends have been reliably identified, and are not artefacts of either how the data has been entered into the registries or how it has been extracted for analysis.

Total clinical trials

Chart 1 presents the total number of clinical trials in New Zealand from 2008 to 2018, projected through to 2021, based on SCOTT[12], MoH HDEC and the ANZCTR (2018) report data. The ANZCT report data indicates steady growth in the number of clinical trials over the last 10 years, whereas the HDEC data suggests a plateauing of the numbers, with both sets of data indicating a figure of about 400 clinical trials having been undertaken in 2018, about 300 of which were specifically intervention studies. SCOTT data pertains only to new medicines which are not approved for use in NZ, with very modest growth in numbers over the past decade.

[10] https://ethics.health.govt.nz/operating-procedures
[11] ANZCTR (2018) p. 58
[12] HRC Standing Committee on Therapeutic Trials (SCOTT) data provided by SCOTT Chairperson

Chart 1: total number of clinical trials in New Zealand 2008 to 2021



Commercial trials

Trends and projections for commercial trials are presented in Charts 2 – 6 below, which indicate the following:

1. There has been steady growth in the overall number of commercially funded and sponsored clinical trials since 2008, which is likely to continue through into the foreseeable future (Chart 2)

2. The data on drug trials is inconsistent (Chart 3). Although there seems to be evidence that the number of drug trials was trending upwards up until 2015, it is difficult to discern whether this is likely to continue into the future given that ANZCTR data suggests a downward trend while HDEC data suggests that growth may have plateaued. (NZHR's analysis of ANZCTR data was able to replicate the 2008 – 2015 figures as provided in the ANZCTR report, and we are therefore confident that our analysis accurately reflects ANZCTR derived data for 2016 – 2018.)

3. The difference between the ANZCTR and HDEC figures requires investigation, especially given that the ANZCTR data reflects all drug trials irrespective of the source

of funding, whilst the HDEC figures report on pharmaceutical industry funded drug trials and therefore should represent no more than a subset of the ANZCTR figures, which appears not to be the case for 2018 (Chart 3). Pharma funded HDEC approved intervention study data, however, is more consistent with ANZCTR figures. Anomalies could be attributable to factors relating to timing and data entry practices. Data provided by the HRC's Standing Committee on Therapeutic Trials (SCOTT), which comprises approvals of trials for new medicines, suggests figures somewhere between the two.

4. The number of HDEC approved pharma funded intervention studies are presented as a subset of the overall data, and represent those approved intervention studies that have been marked with "Pharmaceutical Company" in the "Sponsor" box on the application for ethical approval.

5. NZHR's analysis of clinical trials funded by pharmaceutical companies which are physically located in New Zealand and/or sell pharmaceutical products via Pharmac indicates a clear downward trend since 2013 (Chart 4). The data underpinning this analysis were derived from the USCTR (clinicaltrials.gov), the EUCTR and the ANZCTR. Medicines NZ members spend an estimated $78m on clinical trials[13] (this is not the total spend as non-member companies also invest in the sector). Any decline in the number of clinical trials has potentially significant economic consequences.

6. As growth in device trials appears to have been relatively flat (Chart 5) it may be surmised that the overall growth in commercial trials can be attributed to off shore companies which contract with New Zealand based CROs, but which do not otherwise operate in New Zealand, together with health food and similar companies wishing to verify the purported health benefits of their products.

7. Despite the overall growth it appears that New Zealand is losing ground to Australia, our main competitor for commercial trials. In 2014 New Zealand recorded 33% of the combined Australia/New Zealand total of all commercially funded ANZCTR registered trials, a figure which has steadily fallen to 18.5% for 2018 (Chart 6). This may be attributable to Australia having better financial incentives for industry clinical trials investment.

8. NZHR would have liked to have been able to present trends reflecting the number of participants in clinical trials with the intention of then quantifying the investment gains and/or losses. Unfortunately the readily available sources of information (ie the US, ANZCT and HDEC registers) do not allow for this level of analysis. However the ANZCTR report notes that the median sample size for New Zealand clinical trials overall has declined from 230 in 2006 to 80 in 2015, and that drug trials have also seen a sharp contraction in sample sizes over time, with the median falling by 57 per cent between 2006 and 2015, from 329 to 140.[14] This is despite the fact that there is a strong willingness among the New Zealand public to participate in clinical trials as demonstrated by NZHR polling[15] which reports that:

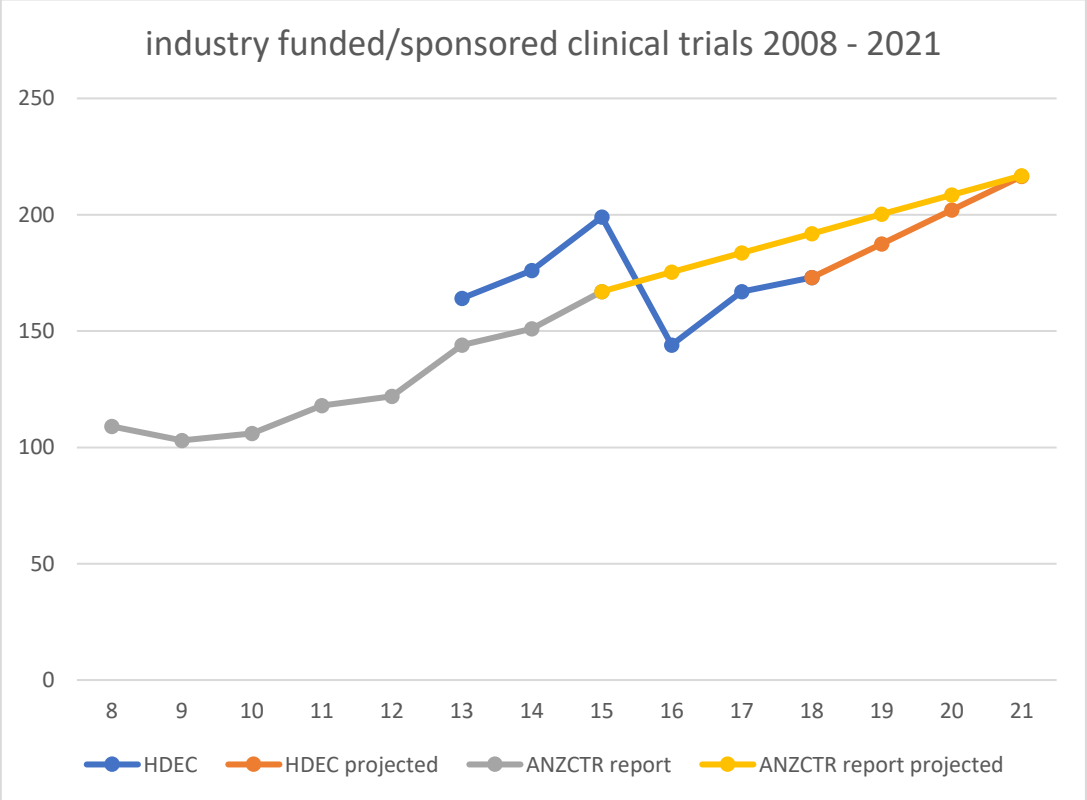
    - 82% of respondents agreed that industry (ie pharmaceutical companies) should invest more in health research

[13] Dixion & Jarvis. *Manuscript in preparation* (2018). Medicines New Zealand.
[14] ANZCTR. 2018. p 37
[15] New Zealand Speaks! 2018 Roy Morgan Research NZHR Opinion Poll (Members' edition).

- 79% agreed that it is important for New Zealanders to be able to participate in clinical trials
- 83% said they would be willing to participate in a clinical trial of a new medicine if they had a condition it could treat
- 66% agreed that there should be more opportunities for new Zealanders to participate in clinical trials for new medicines, and
- 62% agreed that participating in clinical trials for new medicines is as important as donating blood

9. Declining investment also implies declining ability to reap the health and economic benefits of clinical trials. Clinical trial participants can receive high quality, protocol driven health care at the funders expense over many years at considerable saving to the New Zealand public health system. In addition, patients get access to novel medicines that they otherwise would not be able to access through the public health system. The Middlemore Clinical Trials Unit estimates consequential savings to Counties Manukau Health of $1m in 2018,[16] and the hepatitis C clinical trials case study presented in Figure 1 notes savings in drug costs alone of $200m compared with treatment costs of $800m using pre-trial available therapies.

Chart 2: number of industry funded/sponsored clinical trials in New Zealand 2008 to 2021



[16] Middlemore Clinical Trials Trust. Annual Report 2018.

Chart 3: number of drugs trials in New Zealand 2008 to 2021

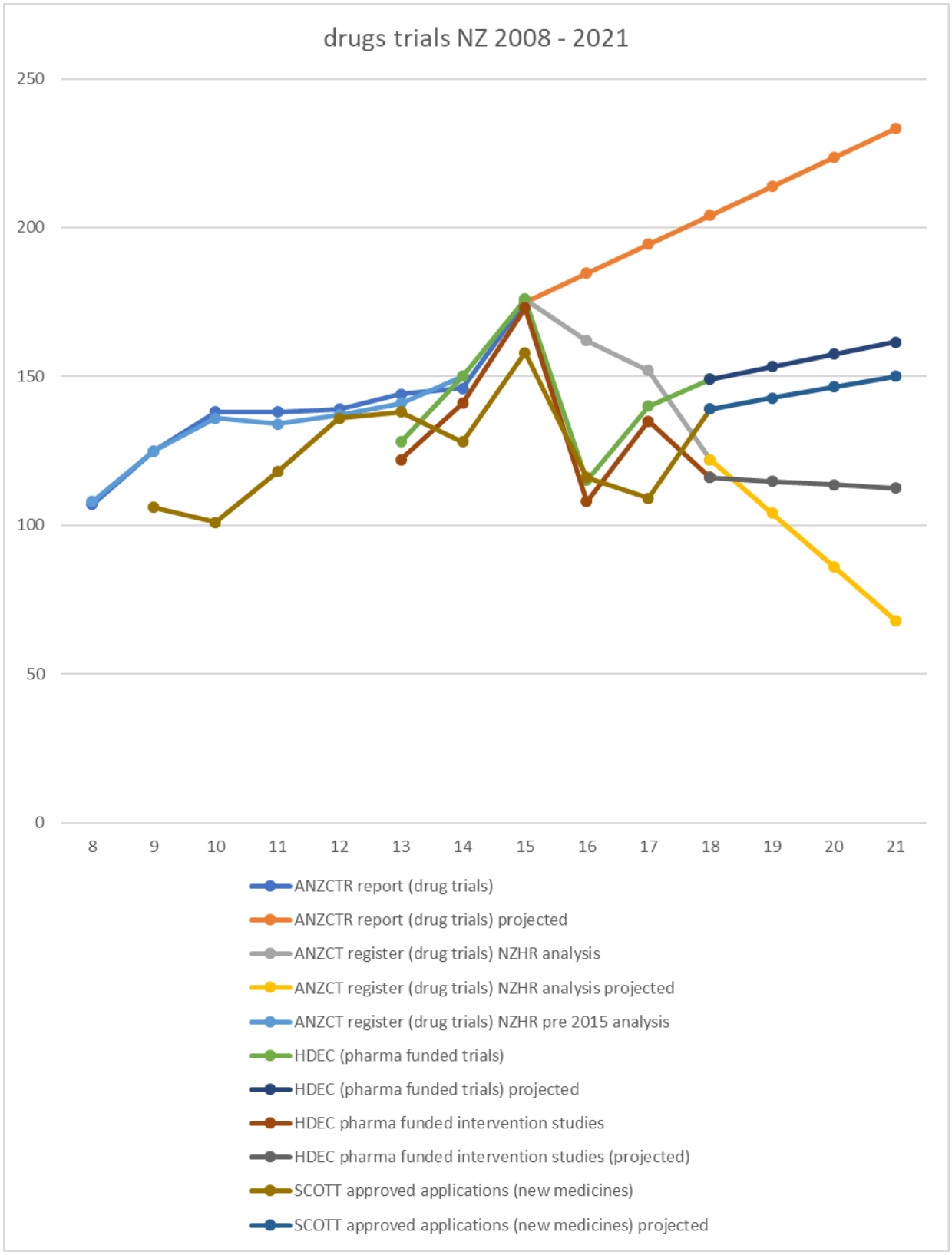


Chart 4: number of clinical trials in New Zealand 2008 to 2021 funded by international pharmaceutical companies located in, and/or which market and sell their products to, New Zealand

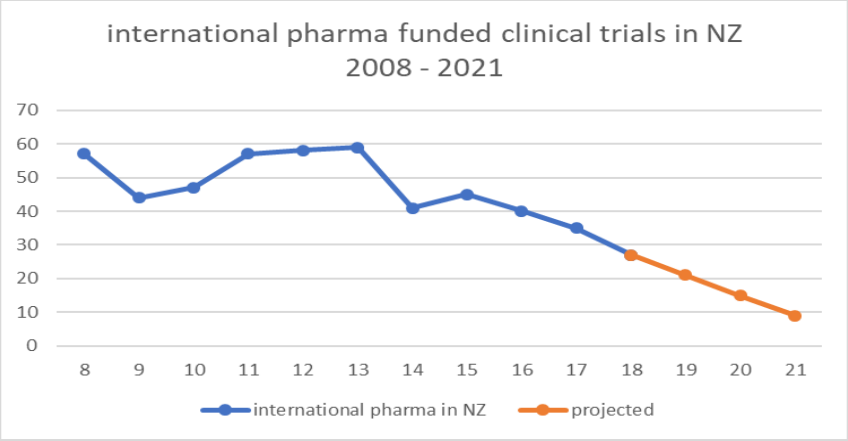


Chart 5: total number of device trials in New Zealand 2008 to 2021

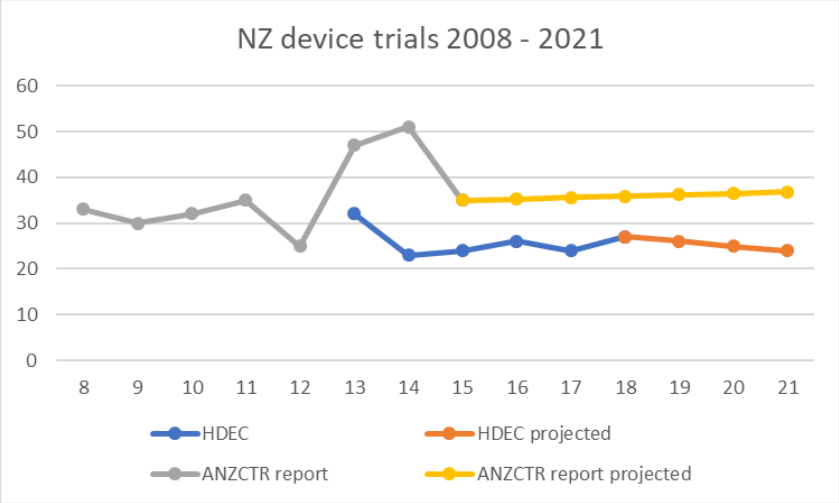


Chart 6: New Zealand clinical trials as a percentage of the combined Australia/New Zealand total 2008 to 2021

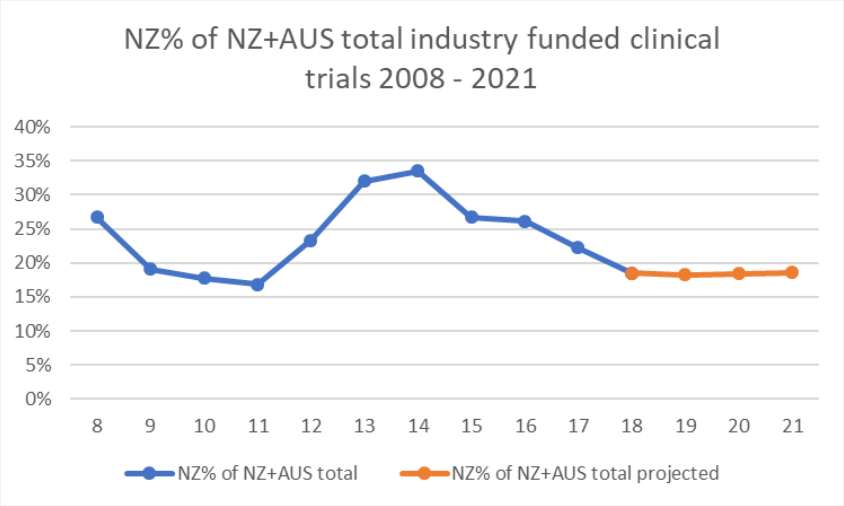
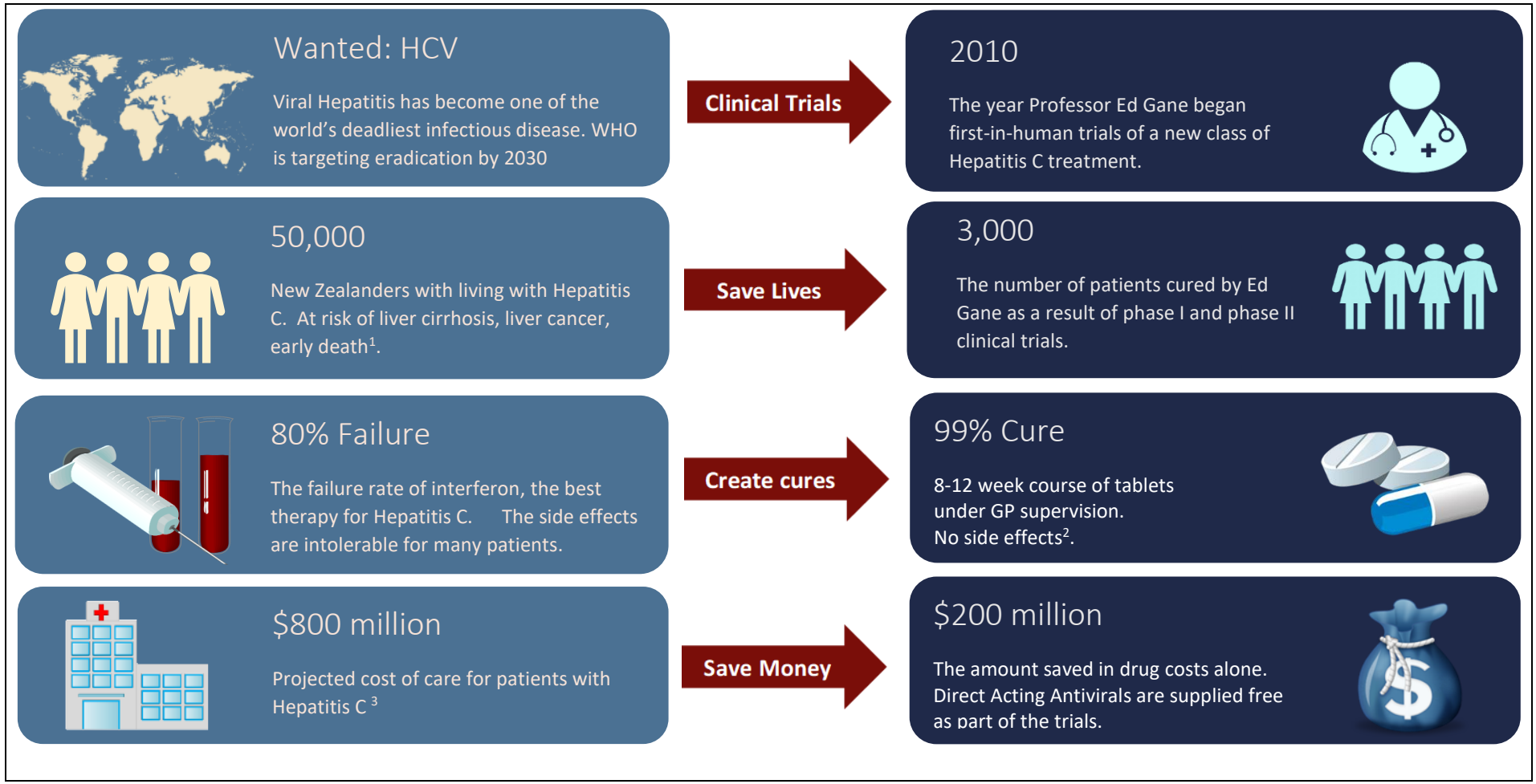


Figure 1: Curing Hepatitis C: A clinical trials case study



1. Ministry of Health estimate 50,000 HCV+ and a further 1,000 new cases per annum https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/hepatitis-c
2. Gane *et al.*, *Lancet Gastroenteral Hepatol*, 2: 805-13 (2017), also Gane *et al.*, *Gastroenterology*, 151: 902-909 (2016)
3. Sheerin *et al.*, The costs of not treating hepatitis C virus infection in injecting drug users in NZ. *Drug Alcohol Rev*, **22**: 159-167 (2003). Note costs are estimated at $166 - $400m based on 25,000 patients. Current patient estimate is 50,000 patients in NZ.

Hospital trials

Trends in New Zealand hospital sponsored clinical trials are presented in Chart 7. The main features of this chart are as follows:

1. Between 2008 and 2012/13 both the ANZCTR and NZHR analyses indicate strong growth in New Zealand hospital sponsored clinical trials, followed by a sharp fall through to 2015.

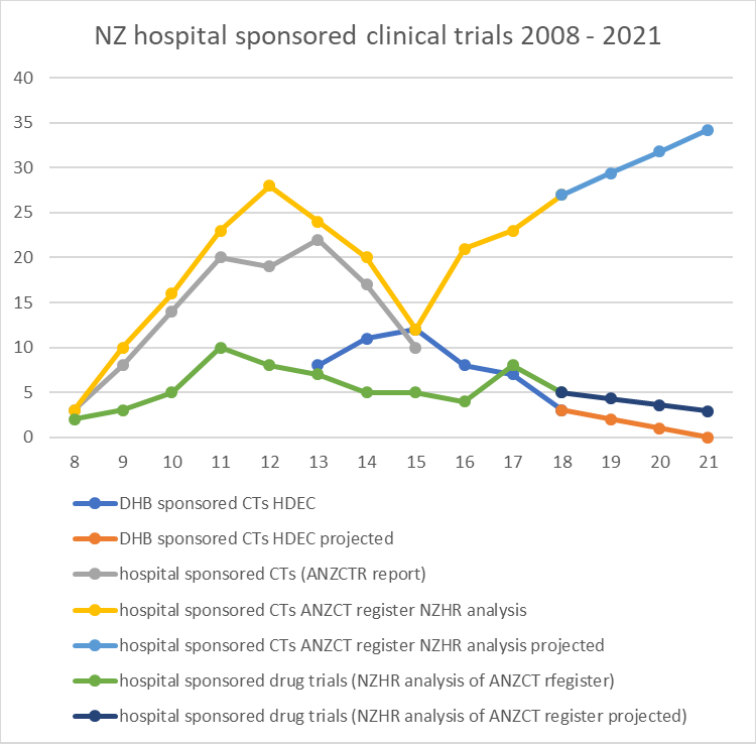
2. NZHR's analysis of the ANZCTR database indicates a resumption of the earlier strong growth, which is projected to continue through to 2021.

3. By contrast HDEC data demonstrates an overall decrease in hospital sponsored clinical trials since 2015 in particular. The difference between the HDEC and ANZCTR data may be attributable to the HDEC data recording only those hospital trials which require ethics approval.

4. Hospital sponsored drug trials in particular would require ethics approval, and NZHR's analysis indicates a decline in the number of such trials since 2011, which is consistent with the HDEC data. Given the decline in industry funded drug trials noted in Charts 3 and 4, this appears to be an area where there is strong potential for future growth.

5. It appears that the post 2015 growth in hospital sponsored clinical trials is attributable to trials involving new or modified procedures and device trials

Chart 7: New Zealand hospital sponsored clinical trials 2008 to 2021



Concluding observations: imperatives for action

The untapped potential for clinical trials in New Zealand is presented in Figure 2 and a menu of options for thinking about "where to from here" is presented in Figure 3.

Figure 2: Clinical Research: New Zealand's untapped potential

Taking the guess work out of healthcare

In medicine, many treatments are ineffective, needlessly expensive, and sometimes even harmful.

Clinical trial networks are groups of clinician researchers asking hard questions, and designing trials to answer them.

ANZICS is a trans-Tasman Intensive Care Network, with 90 sites. Research outputs from ANZICS include many studies that have identified wasteful practices and saved money.

ICUs doing research means the systems in that department are working well, which means better patient outcomes, which means a more attractive, satisfying workplace.

Better patient outcomes

Patients treated at research-active hospitals have better health outcomes:

- Lower mortality rates for NZ cardiology patients participating in clinical trials[1].
- Increased 5yr survival rates for cancer patients in research-active hospitals in Finland[2].
- Increased survival for all ovarian cancer patients in Germany if treated at a research-active hospital[3].
- Better outcomes for all colorectal
- cancer patients in England if treated at a research-intensive hospital[4].

1. Baker et al., *Clinical Trials*, 10: 735-743 (2013)
2. Karjalainen & Palva, *BMJ*, 299: 1069-1072 (1989)
3. Du Bois et al., *Int J Gynecol Cancer*, 15: 183-191 (2005)
4. Downing et al., *Gut*, 66: 89-96 (2017)

Patient Voice

Josephine suffers from rheumatoid arthritis. Two years ago Josephine Tangatopoto had arthritis so badly she could hardly walk. Now she says she is 90% recovered.

"I thought I've got to try this and see how it goes. In the end I loved being part of the trial, the fact that I had the nurse contacting me, reviewing everything. I really listened to the specialist. The tablets have worked and now I don't want to come off them!"

Patient voice case studies provided courtesy of Middlemore Clinical Trials Trust.

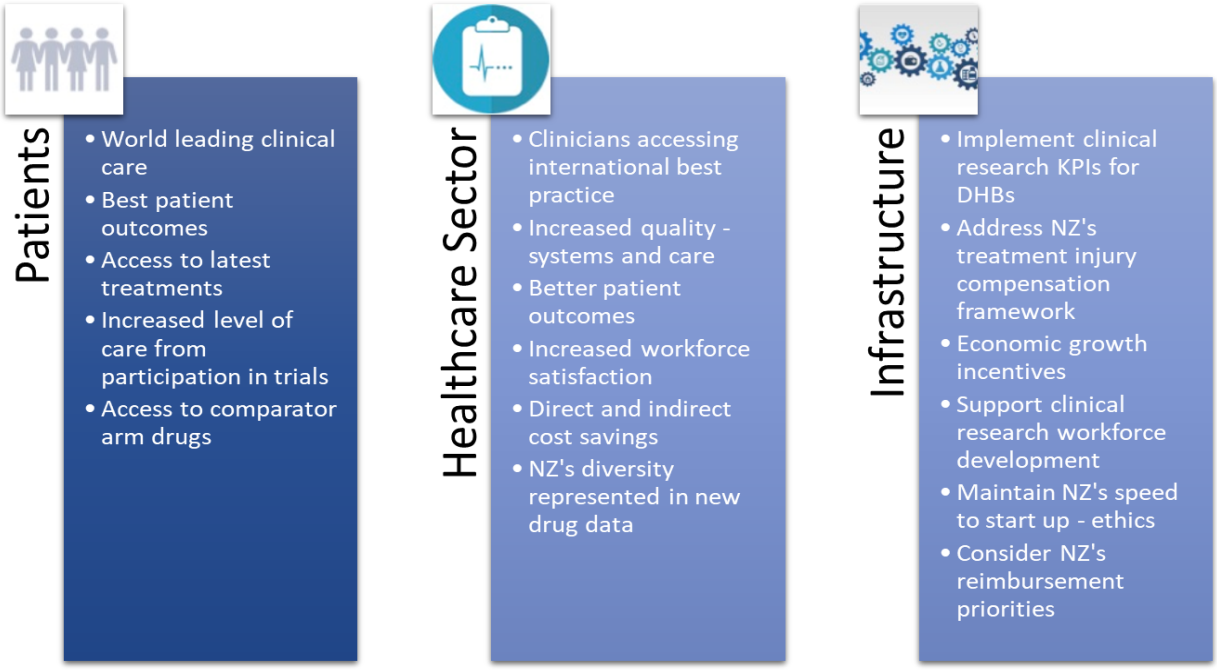
Reduced healthcare costs

Estimated $11m savings in staff costs. Commercial clinical trials saved Middlemore hospital $670K in staff costs in 2017. Using this rate, NZ has saved $11.1M in DHB staff costs in 2017 alone

Medicines NZ members spend an estimated $78M per annum on clinical trials in NZ. Much of this investment covers staff time and patient tests.

Medicines used in clinical trials are provided by the industry sponsor. In 2016 CMH saved $781,229 for the drugs on just 5 blood cancer trials (total trials = 92)

Figure 3: Where to from here?



These options together with the above analyses of both policy implementation to date and data trends indicates the following imperatives for further action:

1. Establishment of a national framework for clinical trial research at district health boards, PHOs and other publicly funded health service entities

2. Set health research/clinical trials specific investment benchmarks and targets

3. Develop clinical trials investment strategies which will enable New Zealand to be competitive with Australia (and other countries) as a place to conduct clinical trials

4. Set targets and develop strategies which will result in public health providers, including DHBs, attracting increased industry investment in clinical trials, especially drug trials

5. District health boards and other publicly funded health service providers be funded to undertake clinical research as a front-line activity

6. Establishment and maintenance of a single accessible register of clinical trials in New Zealand, with sufficient utility, including fields, to enable key elements of clinical trials trends to be reliably analysed and monitored

7. Promote participation in clinical trials through public and physician awareness raising strategies

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