New Zealanders for HEALTH RESEARCH

Ngā Tāngata o Aotearoa mō te Rangahau Hauora

"New Zealand's peak body representing the entire health and medical research pipeline"

Submission on the Medical Council of New Zealand draft statement on informed consent

Introduction

New Zealanders for Health Research (NZHR) was established in November 2015 to bring about increased investment in health research from government, industry and philanthropy. One of our areas of focus has been to increase investment in and the number of clinical trials being undertaken in New Zealand.

In summary, NZHR's submission is that participation in clinical trials gives patients opportunities to benefit from receiving services which are delivered in accordance with best standards of clinical care, that patients should therefore be presented with opportunities to participate in clinical trials as part of the informed consent process, and that the New Zealand health system has unrealised potential for improved performance in this regard.

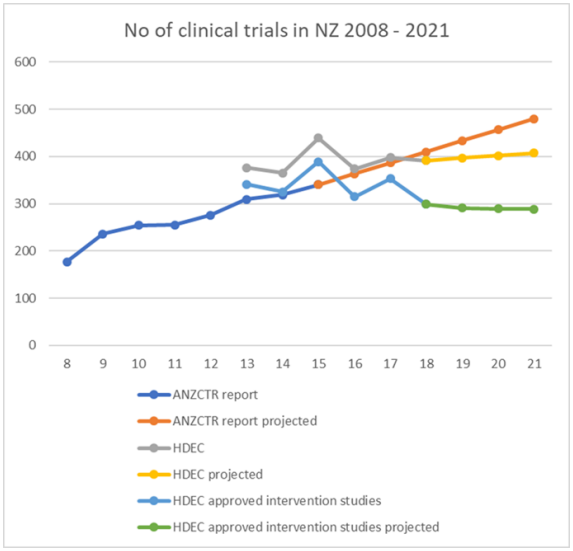
Clinical trials in New Zealand

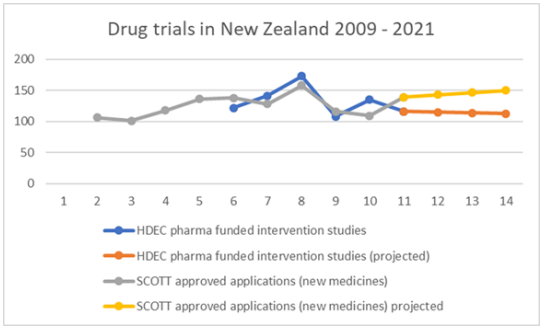
NZHR's Roy Morgan Research 2018 public opinion poll report[1] found that:

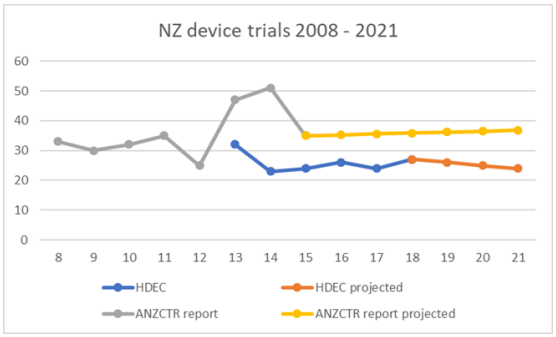
- 14% of respondents reported that they had been asked to participate in a clinical trial
- 8% said that they had participated in a clinical trial
- 79% said that it is important for New Zealanders to be able to participate in clinical trials
- 62% said that participating in clinical trials is as important as giving blood
- 66% said that there should be more opportunities to participate in clinical trials for new medicines, and
- 83% said that they would be willing to participate in a clinical trial of a new medicine if they had a condition it might be able to treat

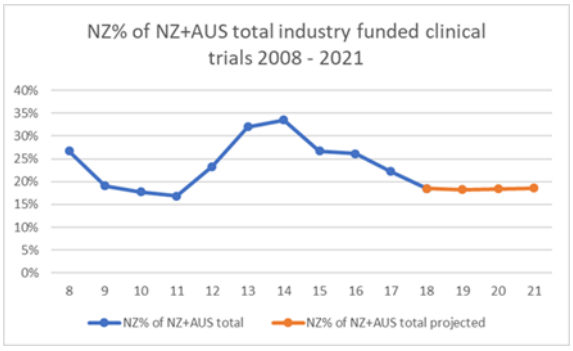
The following trends and projections suggest a gap between New Zealander's beliefs about clinical trials and how the sector has been developing[2] [3]. Successive NZHR stakeholder workshops in August 2017 and March 2019 have identified that there is considerable unrealised potential for growing the clinical trials sector in New Zealand, and the 2017 workshop specifically identified "clinician discussion about clinical trials being a routine aspect of patient care" as an advocacy priority.[4]

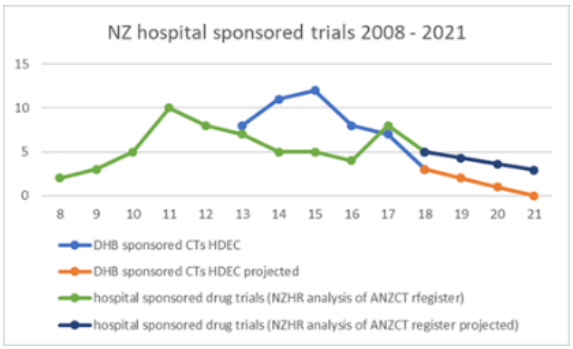
[1] New Zealand Speaks! 2018 Roy Morgan Research NZHR opinion poll. NZHR. 2018. https://www.nz4healthresearch.org.nz/nzhr-2018-poll-report-general-edition/
[2] Clinical Trials in New Zealand: a discussion paper. NZHR. March 2019. https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/02/Clinical-trials-in-New-Zealand-NZHR-op-ed-130319-V2.pdf
[3] The clinical trials landscape in New Zealand 2006–2015. ANZCTR. 2018. http://www.anzctr.org.au/docs/NZ_Report_2006-2015
[4] New Zealand Speaks! 2018 Roy Morgan Research NZHR opinion poll. NZHR. 2018











Clinical trials information and informed consent

We note that the New Zealand Medical Council's draft informed consent document[5] states, inter alia, that:

- ….patients and doctors must believe that the other party is honest and willing to provide all necessary information that may influence any treatment or advice. The doctor needs to inform the patient about the potential risks and benefits of the options available and support the patient to make an informed choice.

- Doctors have a statutory obligation to comply with the Code of Health and Disability Services Consumers' Rights (the Code) [under which] every patient has the right to make an informed choice and to give informed consent…..

- Right 6 of the Code states that every consumer has 'the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive'.

[5] https://www.mcnz.org.nz/assets/News-and-Publications/Consultations/2019-ReviewAppendix-1Draft-informed-consent-statement.pdf

> Specifically, the Code states patients are entitled to … an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and …. notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.

- Before providing information about treatment options doctors should make sure that they are aware of all the reasonable alternatives

- Doctors should obtain separate written consent for research

- Where Informed choice and consent in treatment that is part of research all research must be approved by an accredited ethics committee before patients are invited to participate and give consent to involvement in the study.

Although it could be inferred from these statements that information about clinical trials should be included in any informed consent discussion which includes an "explanation of the options available", NZHR submits that the New Zealand Medical Council's informed consent document should include a specific requirement for doctors to have a discussion about clinical trials with patients when discussing treatment options.

This is important (and too important to leave to chance) not only because it would be consistent with patient expectations[6], but also because it would give patients opportunities to:

- receive care which is consistent with international best practice,
- have access to the latest treatments,
- experience outcomes that are better than currently prevailing standards of care (even on placebo)
- develop significant knowledge into their own illness or disease
- experience the feeling of helping future generations, and
- access physicians who it is thought practice medicine 5 years in advance of their non research colleagues.[7] [8]

Doctors can access information about clinical trials in New Zealand from the Australia and New Zealand Clinical Trials (ANZCTR) Register[9], and the Medical Council itself could consider a regular communication with doctors to notify them of any new notifications of clinical trials as they are posted on the ANZCTR (and other) registers.

In developing this submission we have consulted with our partners and members as set out at the end of this document (from whom we derive 100% of our funding).

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[6] New Zealand Speaks! 2018 Roy Morgan Research NZHR opinion poll. NZHR. 2018
[7] Clinical Trials in New Zealand: a discussion paper. NZHR. March 2019
[8] Maximising the benefits of clinical trials. Dr. Edward Watson. Middlemore Clinical Trials. Presentation to NZHR Health and Prosperity through Clinical Trials Workshop. 22 March 2019. https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/04/7.-Ed-Watson-NZFHR-MMCT.pdf
[9] http://www.anzctr.org.au/

NZHR partners and members

Platinum

Gold

Silver

Bronze

Chrome

Foundation