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"

NZHR "Health and Prosperity through Clinical Trials Workshop" 22nd March 2019 summary

Welcome

NZHR Chair Graham Malaghan welcomed everybody to the workshop, noting that; NZHR was established in November 2015 to lift government, industry and philanthropic investment in health research; is governed by a Board comprising a representative cross section of sector leaders; and is wholly supported by the partners and members presented at the end of this document.

Clinical Trials Yesterday Today and Tomorrow.

Chris Higgins. (NZHR Chief Executive).

- The most recent comprehensive review of the clinical trials sector was undertaken by Parliament's Health Committee in 2011.

- A key recommendation for health research to be considered a DHB front line activity was not by supported by the then government.

- Implementation of the Committee's recommendations has been ad hoc and patchy, but being progressed through

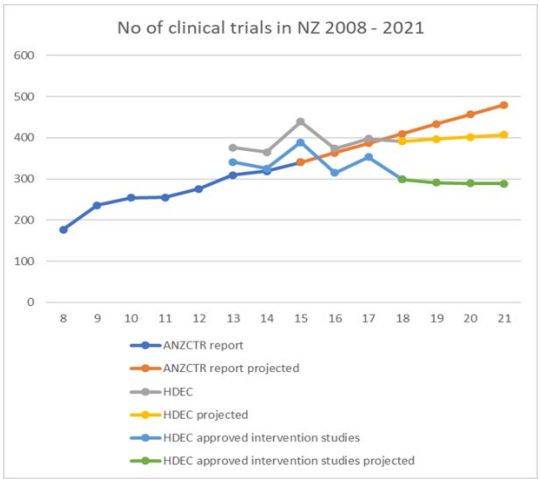
    - The Health Research Strategy
    - The government's R&D investment strategy
    - NEAC's review of health research standards
    - The proposed new therapeutics products legislation

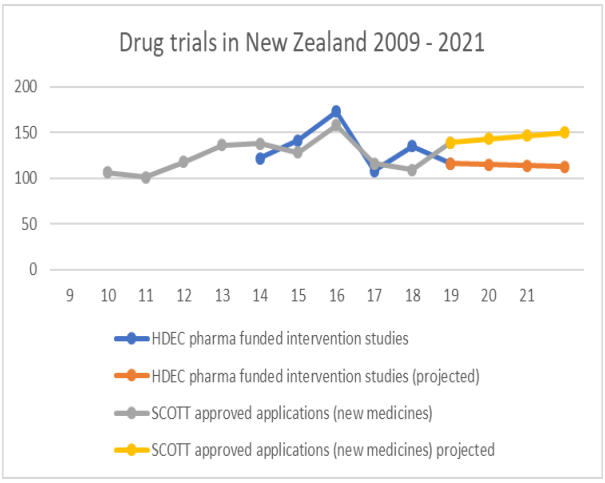
Proposed required actions:

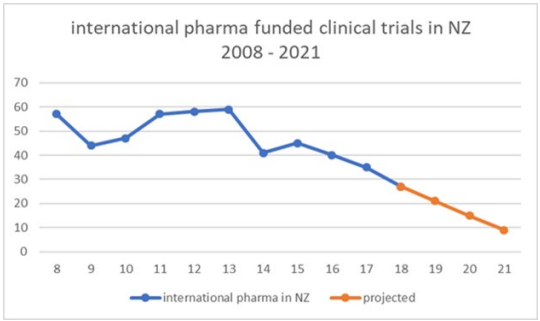
1. Establishment of a national framework for clinical trial research at district health boards, PHOs and other publicly funded health service entities
2. Set health research/clinical trials specific investment benchmarks and targets
3. Develop clinical trials investment strategies which will enable New 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

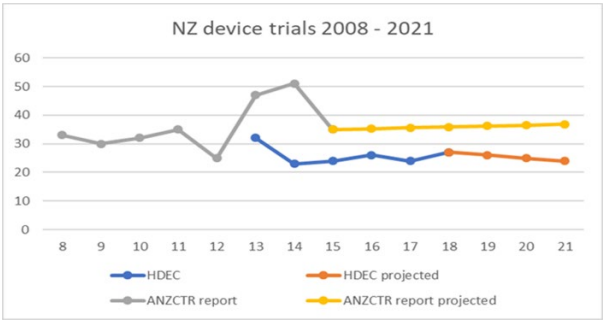
6. Establishment and maintenance of a single accessible register of clinical trials in New Zealand, with sufficient utility, including fields, to enable key elements of clinical trials trends to be reliably analysed and monitored
7. Promote participation in clinical trials through public and physician awareness raising strategies

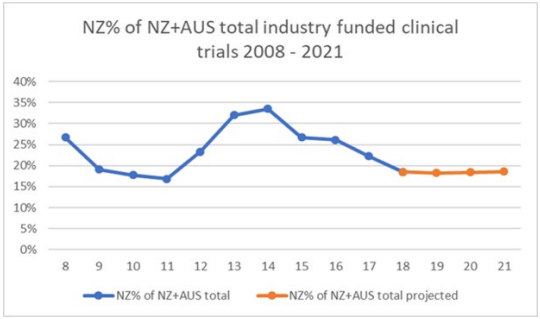
Selected key trends are presented below:

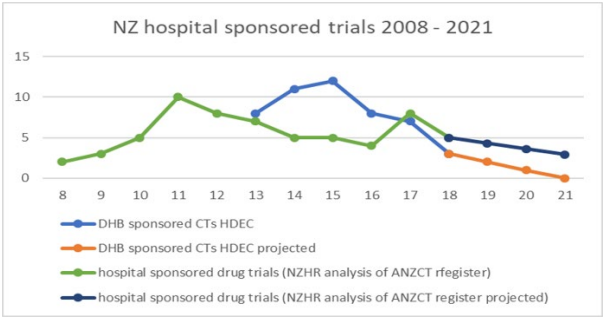












Maximising the benefits of research and clinical trials.

Panel comprising Michelle Sullivan (NZHR advisor), Julia Matheson (Director of Clinical Trials, Southern Clinical Trials, Christchurch) and Mike Williams (Director, Lakeland Clinical Trials, Rotorua)

- Australian sector worth $1.1 billion; 1,360 trials; and 6,900 jobs (2015, LEK Consulting).Includes direct trial costs, flow-on benefits, multiplier effects
- New Zealand sector generates $384M in GDP per annum (Medicines NZ, 2017); 340 trials in 2015, (2018 HRC/MoH, ANZCTR).

- Community base clinical trials units such as LCT are viable option which can simultaneously tap into local communities, local GP networks and the international community

- Economic benefits of clinical trials include:
  - Generation of export revenues
  - Avoidance of public healthcare costs
  - Access to new medicines at no cost
  - Productivity gains

- New Zealand's competitive advantages include:
  - High-quality research facilities
  - Efficient ethics and regulatory framework
  - Can accommodate seasonal differences
  - Diverse participant recruitment pool

- Challenges for New Zealand:
  - How do we stay competitive?
  - Biggest risks in the commercial trials space?
  - Biggest opportunities?
  - DHB engagement, ACC coverage, metadata/informatics, international outreach (BIO2019)
  - Therapeutic Products regulatory regime – friend or foe?
  - Patient pool, regulatory environment, ethics, tax incentives

Implementing the Health Research Strategy (NZHRS)

Lucy Pomeroy (Senior Research Investment Manager, Health Research Council) and Nic Aagaard (Principal Advisor, Ethics, Quality Assurance and Safety and Health System Improvement and Innovation, Ministry of Health)

- The NZHRS has created a unique opportunity for transforming how health research is embedded within the health and science sectors.

- The potential of clinical trials was previously recognised in the 2011 Clinical Trial Inquiry. The NZHRS extends this thinking by focusing on achieving synergy between clinical research, workforce, practice and policy.

- This is a complex undertaking, efforts to date have focused on taking time to building relationships and connections to support implementation, and do the critical thinking underpinning future policy development.

- Within the HRC's draft prioritisation framework, clinical trials most strongly map to Domain 2, focused on enhancing a people centred health system, and there is specific reference to Improving diagnostics and treatments and supporting clinical trial infrastructure.

- Approximately 20% of HRCs budget is invested in clinical research and there are flexible budget caps and timeframes for clinical trials.

- HRC's first investment plan is due mid-2019 and will signal investment intentions for the next financial year.

- Leadership is required to promote high quality, high value research as a cornerstone of the NZHRS (for clinical trials this means that research priorities are justified, research design, conduct and analysis is robust, and that trial information is accessible and useable throughout the trial lifecycle).

- Important to foster connections with ACTA and Australia's NHRMC

- A significant part of the work that has been conducted in 2018 was about building relationships between agencies, in order to work together, as well as scoping out the detail of implementation across a diverse set of strategic goals.

- A joint work program was compiled in December 2018 to provide an overview of work in support of the HRS, across each agency. This is an important step in working with the different levels of governance, and creates a platform for each agency to get to work.

- The Ministry of Health is taking the lead on:
  - Creating a vibrant research environment in the health sector by:
  - strengthening health sector participation in research and innovation
  - strengthening the clinical research environment and health services research
  - Building and strengthening pathways for translating research findings into policy and practice by enabling and embedding translation across the health sector.

- To ensure delivery of the Ministry's NZHRS obligations, oversight and management has been allocated to Keriana Brooking, Deputy Director-General (DDG) Health System Improvement and Innovation Directorate. The Ministry is also advertising for a general manager who will look after NZHRS implementation across the business units of the Ministry

Measuring trends and progress

Lucy Pomeroy and Chris Higgins

- None of the available data sources capture the total number of clinical trials
- There is currently no single comprehensive source of data
- All clinical trials which have received ethics committee approval are required to be registered with a WHO primary registry; 18 per cent of all registered studies recruiting in New Zealand between 2006 and 2015 are registered on WHO primary registries other than the US and ANZ CTRs
- All figures reliant upon how users completed the register fields or ethics applications submissions
- The HRC has been the key NZ contact for the ANZCTR since it was established in 2005
- The ANZCTR Landscape report provides an important picture of clinical trial activity in NZ (while recognising there are limitations associated with coverage, compliance and the prospective nature of the data).
- Australian Government has recently invested in a review of the Registry and consideration of a new generation registry.
- A key issue of relevance to the future development of the registry is data quality, updates and sharing of results and research data.

- The ANZCTR is a valuable source of metrics regarding the performance of trials. The accuracy of the information relies not only on prospective registration but on annual updates to registry information and ultimately timely reporting of results.

Maximising the benefits of research and clinical trials (cont)

Ed Watson, Chief Executive, Middlemore Clinical Trials

Benefits for patients:

- Outcomes better than standard of care (even on placebo)
- Access to novel medicines and therapies (especially in cancer and diabetes)
- Development of significant knowledge into their own illness or disease
- The feeling of helping future generations
- Access to physicians who it is thought practice medicine 5 years in advance of their non research colleagues.

Benefits for clinicians

- Involvement in global studies
- Access for their patients to novel medicines that are otherwise unavailable.
- Develop experience in novel medicines and new classes of medicines
- Involvement with regional collaborative groups to research specific issues
- Commercial trials as per MCT model generate money for the researcher to spend on grant studies, collaborative group and even investigator initiated studies which is really what motivates most hospital researchers

Benefits for hospitals

- Attraction and retention of leading clinicians and other staff
- Revenue generation (OPEX and rent)
- Cost offsets.
- Engagement with research organisations such as universities

Benefits for NZ Inc

- Direct Foreign exchange-
    - Commercial clinical trials is an export business
    - Globally between $US30-40 billion is spent annually on health research. Currently NZ attracts about $30-40 million
- Develop links with international research companies. This is where our biotech companies will come from
- Big pharma are looking to partner with research organisations instead of doing it themselves.
- Access for the population to new chemical entities
    - Immunotherapies cost> $150,000 p.a per patient
    - CAR T cell reengineering of immune cells costs >$400,000 per patient
- Attract back to New Zealand some of our brightest and best minds in the medical research field

Therapeutics products legislation

Chris James (Group Manager, Medsafe, Ministry of Health)

- Purpose is to protect personal and community health by:
    - ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and

- regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products.

- The likely benefits of therapeutic products should outweigh the likely risks associated with them

- A product is a therapeutic product if:
  - it is intended for use in, on, or in relation to humans for a therapeutic purpose; or
  - it is specified in the regulations to be a TP; or
  - it is intended for use as an active ingredient of a medicine.

- A naturally occurring thing …. may become a TP if it is changed from its naturally occurring state…..but…a product that would otherwise be a therapeutic product is not a therapeutic product if it is a natural health product.

- The following are therapeutic purposes:
  - preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury
  - influencing, inhibiting, or modifying a human physiological process
  - testing the susceptibility of humans to a disease or an ailment
  - influencing, controlling, or preventing human conception
  - testing for human pregnancy
  - investigating, replacing, modifying, or supporting part of a human's
  - anatomy
  - supporting or sustaining human life
  - disinfecting medical devices

- The legislation would regulate:
  - Medicines
  - Active ingredients of medicines (AMIs)
  - Medical devices
  - Type-4 products.

- A clinical trial for a medicine means:
  (a) involves administering the product to, or using it on, 1 or more individuals (**subjects**); and
  (b) undertaken to obtain information about its quality, safety, or efficacy or performance by doing 1 or more of the following
    (A) discovering or verifying its clinical, pharmacological, or other pharmacodynamic effects
    (B) identifying any adverse reactions to it
    (C) studying its absorption, distribution, metabolism, or excretion; and
  (c) to which 1 or more of the following apply
    (i) the assignment of each subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice:
    (ii) the decision to administer or use the product is taken together with the decision to include the subject in the study
    (iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the subjects.

- Conducting a clinical trial would require a licence which would spell out the scope of what is permitted and also authorise the supply of the unapproved trial product for use in that trial

- Criteria for granting a licence would include:
  - The resources (includes human & financial, premises, equipment, procedures) are adequate & suitable resources
  - Relevant persons having knowledge and ability to comply
  - ethics approval

- The transition period for the new scheme likely to begin around late 2022 or early 2023.

Submissions on the proposed legislation due by 18 April

NEAC review of health research standards

Nic Aargaard

- NEAC is amending the original consultation document to:
  - Ensure introductions consistently link back to partnership of principles
  - Be more consistent in embedding of Māori bioethics (Te Ara Tika)
  - More fully include disability perspectives and research
  - Be more inclusive of LGBIQ+ perspectives
  - Better address legal issues in relation to non-consensual research (both cluster design and clinical trials with adults who lack capacity to consent)

- NEAC are meeting on 30 April to review the next draft. Aim is to launch the Standards late July with a month lead in period before they are active

Next steps

Key themes which were identified by workshop participants as priorities for NZHR's advocacy programme were:

- How underfunding of the sector (Pharmac, DHBs, etc) impacts on clinical trials
- Incentivising clinical trials through tax credits
- DHB efficiency/capability and prioritisation of clinical research
- KPIs for research in DHBs and PHO's
- Environmental Protection Agency process when genetically modified organisms are involved in studies
- Data – using big data and data access
- The impact of Pharmac's reimbursement model on clinical trials
- CRO auditing and privacy of trial participants' personal information
- ACC compensation in the event of harm resulting from clinical trials

1st April 2019

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