Clinical Trials and Industry: A Perspective from NIHI

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National Institute for Health Innovation

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THE UNIVERSITY OF AUCKLAND
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Affiliations

I am an employee of the University of Auckland

I lead a research group operated by Auckland UniServices Ltd.

Disclosure

In 2013, McNeil AB, Sweden, a manufacturer of smoking cessation medications, provided hotel accommodation when I gave a talk to staff.
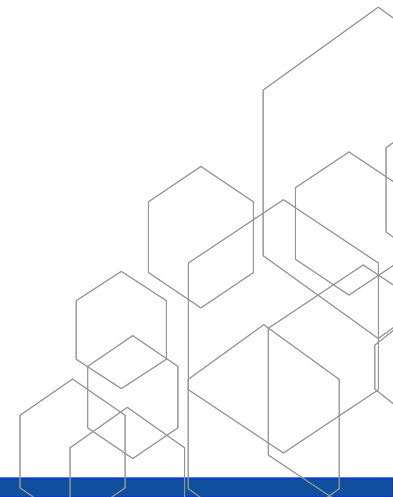
I have grants from the HRC, Ministry of Health and University of Auckland.

Outline

- Introduction to NIHI

- What do we mean by "Industry"?

- Engagement with industry at the organisational / institutional level – issues, challenges and solutions.

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Academic centre focused on health innovation

Partnerships with:
- Community organisations
- Healthcare providers
- Policy makers
- Commercial organisations
  to provide evidence for health improvement

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- 26 years ago NIHI began as CTRU, built upon large multicentre investigator-initiated Phase III cardiovascular trials funded largely by Big Pharma
- Now a Faculty centre operated through UniServices Ltd., the commercialisation arm of the University of Auckland (revenue > $100m/yr)
- 2009 - peak 85% of research income from HRC
- 2013 - merged with nihi to become NIHI – added connection with Health IT sector
- 50+ researchers and support staff
- On-going focus on intervention-oriented research (typically RCTs) addressing leading health risks and issues in NZ and globally
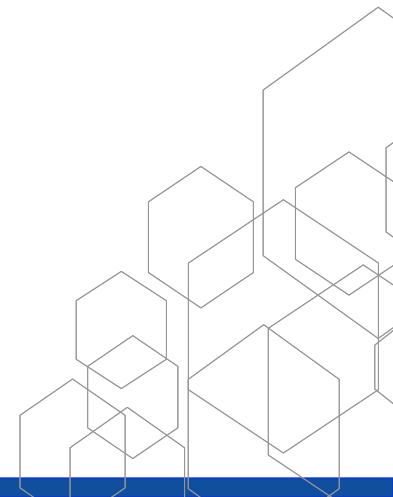
Areas of research expertise

- Heart Health
- Nutrition
- Physical Activity
- Addictions
- Health Informatics & Technology
- Clinical trials support and IT development services

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Push away from Pharma

- Exit of Pharma from NZ

- Decline in Pharma funding of large CVD trials

- Loss of 'magnet' PIs offshore

Pull towards other areas

- New wave of researchers with interests in 'pragmatic public health trials' with strong links to policy and healthcare provision

- Public good research funding supportive of broad research focus on NCDs and increasingly, health IT

- Decline in public good research funding pool is a challenge to sustainability

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- ## Blurred lines – Big Pharma and …
  - Big Food and Agra
  - Biotech
  - Alternative products – e.g. nutriceuticals, natural remedies
  - Tobacco and other 'dangerous consumptions'
  - 'Digital medicine'
  - Telecoms, Imaging, Gaming …
  - Insurance and Healthcare Industries
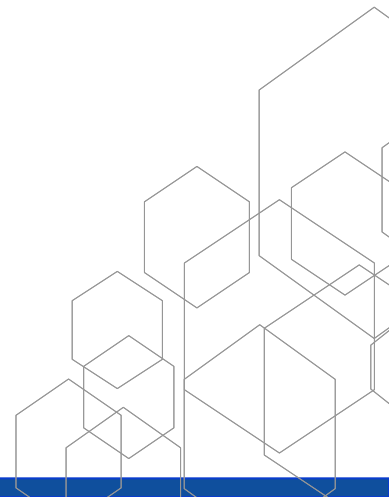
UniServices

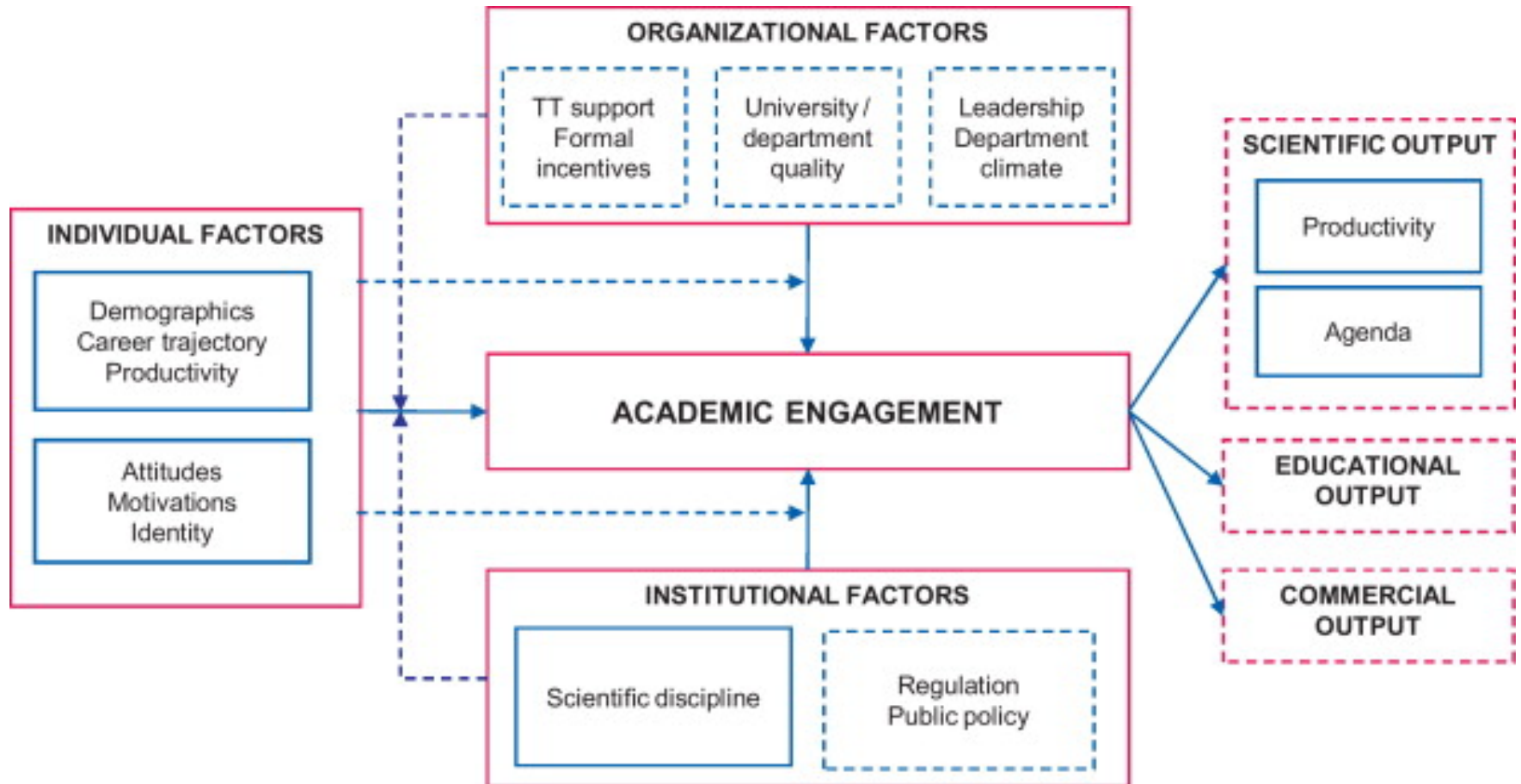Auckland UniServices Limited

**RESEARCH FUNDING AGREEMENT
BETWEEN**

AUCKLAND UNISERVICES LIMITED

A N D

PHILIP MORRIS USA

1994

An analytical framework of external engagement by academic researchers

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- Drivers to engage with industry & commercialise research discoveries:
  - **top down** (government policies, university incentives for IP creation and academic entrepreneurship)
  - **bottom up** (researcher interests).
- NZ Tertiary Education Strategy 2010-2015 emphasises need for better linkages between universities and industries - but says little about potential for COI.
- Rise of business culture and values in universities and of industry-academia ties globally.
- Financial interests of an organisation may encourage and reward ties with industry and affect the conduct, review or oversight of research.

- Aimed to investigate how to improve NZ's environment to support innovation via clinical trials
- Terms of reference included:

"Benefit to NZ patients through clinical trials as well as to the NZ innovation system, health system **and economy**."

Tensions

Institutional imperative

vs.

Organisation/investigator research interests and values

vs.

Organisational viability/ researcher career survival

Benefits of industry-sponsored research

vs.

Risks of institutional, organisational and researcher capture.

- Limited scientific and ethical literacy in 'new' industries
  - poor understanding of scientific processes, methods and ethical frameworks in many industries e.g. assumption that research will support product vs. researcher equipoise
- **May apply equally to universities and their commercialisation organisations as to industry**

Dealing with tensions and challenges

- Awareness of risks of engagement with industry

- Researchers need to be clear re. own values and 'bottom lines' through reflection and self-assessment

- Organisational 'climate' - explicit principles, strategies and guidelines in relation to industry engagement.

- Researchers should engage with institutions and organisations to ensure understanding of researcher's / organisation's principles, and attitudes towards involvement in industry-supported research.

- Researchers' role in educating public about science.

Dealing with Industry

From outset

- Know 'bottom line' - be prepared to walk away at any time if integrity at risk.

- Be transparent about all involved individual and organisational interests.

- Be clear about your proposed uses of trial data - specify details of all proposed analyses and publications from outset.

- Be clear around role of sponsor vs. investigator; - ensure firewalls are in place

- Do the basics - trial registration, ethics guidelines, codes of conduct, GCP .

- Seek expert legal advice early

- Agree on processes for dispute resolution.

- Establish 'cast iron' agreements around right to publish, media coverage and use of product/company name in media, in particular in the event results are negative.

Conclusions

- The nature of 'Industry' in health research is shifting, creating new risks to research integrity.

- Engagement to be undertaken only if well prepared

- Can't assume shared scientific or ethical literacy or values with industry - or even within own organisation.

- Vigilance needed – self, organisation / institution.

- Is a Sunshine Act needed for organisations and institutions?

Contact

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