
# The value of clinical research with modern medicines in New Zealand

## Economic contribution and wide-ranging benefits

**NZIER report to Medicines New Zealand**

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# Key points

## Clinical research makes a significant direct and indirect contribution through development of modern medicines in New Zealand

- The total economic contribution of clinical trials of new medicines exceeded $150 million per year in the period 2013 to 2018.
- New Zealanders participated in at least 100 such clinical trials each year and these trials employed in excess of 700 people.
- These trials directly contributed over $169,000 per employee to the economy which is more than the clinical sector employee contribution in the UK, Ireland and Thailand.
- In 2018 this sector also supported other sectors by purchasing $44.0 million of supplies and indirectly supporting 222 jobs.

## There are also benefits to the health system from conducting clinical trials in New Zealand

- Trials promote a research culture in the health system and stimulate the translation of evidence-based knowledge into clinical practice.
- Trials support recruitment and retention strategies for high quality health professionals seeking professional development opportunities.
- Trials give students in the health professions opportunities to learn and apply knowledge of the latest technologies.
- Participants in later phase clinical trials of new medicines may get early access to promising treatments.
- Research trials can save the health system money – patients in trials receive intensive clinical assessment and oversight at the expense of the trial Sponsor and they may have better health outcomes due to participation in research.

## Economic contribution from these trials has been relatively static

- The mean direct contribution to GDP over the period 2013 to 2018 was $146.3 million, with peak years noted in 2013 and 2015.
- Direct contribution to GDP appears to have stabilised in 2017 and 2018 when it was $127.0 million and $127.4 million, respectively.
- Of note, over the period reviewed there appears to be a trend toward increasing numbers of Phase I trials and decreasing numbers of Phase III trials being conducted. The number of Phase IV trials conducted are less than 5% of the total number of trials over the entire period.

## An opportunity lost?

- The relatively flat contribution of trials of modern medicines in recent years means there is an opportunity lost to gain direct economic benefits through clinical trial research in New Zealand.

- With the number of Phase IV trials (of unapproved medicines) conducted in New Zealand already less than 5%, if the trend continues of a reducing number of Phase III trials in New Zealand, the opportunities for patients and clinicians to have access to potentially promising modern medicines may also be lost.

## New Zealand needs better quality clinical trials data and a functioning clinical trials network

- Trials can be registered across various registries, which has led to missing registrations, insufficient guidelines around clinical trial data management and overall, poor quality data.
- Promoting the transparency of reporting results and regular publications of funding can inform stakeholders of the benefits of clinical trial research and the opportunity afforded to New Zealand by conducting clinical trials.

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# 1 The ask

NZIER was asked to determine the economic contribution of clinical trials to the New Zealand economy in terms of:

- direct economic contribution
- indirect economic contribution
- total economic contribution.

We were also asked to provide a qualitative assessment of the benefits to New Zealand's health sector from conducting clinical trials in New Zealand. To ensure reliability of our analysis, we have narrowed our scope to *pharmaceutical-type* clinical trials recommended for approval by the Health Resource Council's (HRC) Standing Committee on Therapeutic Trials (SCOTT) (henceforth, 'SCOTT trials').[1] These trials are exclusively of interventions that meet the definition of "new medicines" under New Zealand legislation. This means our estimates are conservative as they do not capture the entire clinical trials sector in New Zealand.

### Context

A 2018 report released by the Australian New Zealand Clinical Trials Registry found that numbers of clinical trials had been growing steadily over the past decade in New Zealand (Australian New Zealand Clinical Trials Registry 2018) but there is limited research in New Zealand around the contribution of clinical trials to the New Zealand economy. This is in part due to the data limitations as discussed below. This study seeks to set out what we can establish from existing data and what we would like to know from future studies. Quality of data needs to improve so that future reports of this nature can be more accessible.

# 2 Data source and limitations

All clinical trials conducted in New Zealand should be registered prior to the commencement of participant recruitment with an approved Clinical Trial Registry (National Ethics Advisory Committee 2019; Health and Disability Ethics Committee 2020). However, there is no single registry that captures all trials which are conducted in New Zealand – in fact the choice of Clinical Trial Registry is at the discretion of the trial Sponsor and/or Lead Investigator. Consequently, although many clinical trials, which are exclusively being conducted in New Zealand (or in Australia and New Zealand), are registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR), international multicentre trials which New Zealand is participating in are predominantly registered on other registries including the US's ClinicalTrials.gov registry. In fact, in some cases single trials are registered on multiple registries leading to the possibility of double-counting trials when registry data sets are combined. Additionally, recruitment data reported on Clinical Trial Registries is ordinarily not presented on a country-specific basis but rather on the basis of global targets

[1] The SCOTT operates under Section 30 of the Medicines Act and is responsible for the scientific assessment of clinical trial applications for pharmaceutical-type new medicines and makes recommendations for their approval.

or actual global recruitment, meaning accurate New Zealand-specific participant recruitment data for all trials conducted in New Zealand cannot be derived from Clinical Trial Registry sources.

Consequently, we have limited our scope to analysing SCOTT trials only, which focus exclusively on new interventions. Using SCOTT trials as opposed to using trials from ANZCTR will yield more conservative estimates of the economic contribution to the New Zealand economy of clinical trials but will be more robust.

Medsafe, which has responsibility under delegated authority from the Director-General of Health for the administration of the trial application and approval process, provided yearly (2013 to 2018) unit record data for trials reviewed and recommended for approval by SCOTT. For each trial we were provided with its:

- title
- phase (I–IV, Generic/bioequivalence or Early Access Protocol)
- trial Sponsor identity and entity type
- number of participants scheduled to participate
- number of participants that actually participated.

This data was obtained by Medicines New Zealand under the Official Information Act. Trials in the dataset provided were categorised as commercial or non-commercial according to their Sponsor, and were coded by therapeutic area condition category using an internationally recognised Health Research Classification System (e.g. cancer, skin, inflammatory, etc.) (Health Research Classification System n.d.) by personnel from Medicines New Zealand. The list of trials in this dataset was also reviewed independently by an expert clinical researcher from the New Zealand Association of Clinical Research (NZACRes).

A cross-check of participant numbers which appeared unusual given the trial phase or therapeutic indication and/or likely to be erroneous due to typographical error was performed for individual line entries in the dataset. Participant numbers were validated to the extent possible against publicly available information from trial registries and publications, and conservative recruitment estimates were made when necessary.

After these reviews and validation checks we had confidence in the number of participants *scheduled* to participate, but not the number of participants that actually participated. So, we used the number of participants **scheduled to participate** as a proxy for the actual number of participants in our analysis.

Between 98% and 100% of the trials in our SCOTT dataset are Phase I–III trials of medicines. This is because only trials of interventions that meet the definition of “new medicines” under section 3(3) of the Medicines Act 1981 (New Zealand Legislation 2018) require regulatory approval and are submitted to SCOTT for review. Trials of medicinal products already registered in New Zealand do not require approval, which means that few Phase IV trials require approval and are submitted to SCOTT. Likewise, trials of medical devices do not require approval. Additionally, although trials involving highly specialist therapeutic technologies such as xenotransplanation and gene therapies do require regulatory approval they are reviewed by the HRC’s Gene Technology Advisory committee (Ministry of Health 2018; HRC Gene Technology Advisory Committee 2007) rather than the SCOTT and thus are also not included in the SCOTT trials dataset. This means a key limitation of our report is



that we cannot estimate the value to New Zealand of clinical trials of all types of modern medical interventions.

# 3 Broad benefits to New Zealand from clinical trials

Clinical research in New Zealand is broad in scope:

- The full spectrum of interventional studies takes place in New Zealand including all phases of the medicines development process (Phase I first-in-human trials through to Phase IV post-approval studies), as well as studies of medical devices, natural health products, and other interventions (diet, physiotherapy etc).
- There are research studies taking place around the country and at all levels of the public health system from primary care to intensive care as well as in private purpose-built research facilities.
- New Zealand researchers include clinicians and other health professionals employed within our hospitals and general practices, academics employed by New Zealand Universities, and professional clinical researchers employed by Private Commercial and Non-commercial Research Units.
- In addition to activity taking place at research sites (hospitals, clinics etc) a number of international Contract Research Organisations (CRO) have local offices and personnel in New Zealand (e.g. Syneos Health,[2] IQVIA,[3] Covance,[4] etc.). These companies undertake project coordination and clinical trial monitoring responsibilities on behalf of the study sponsors. New Zealand companies and independent consultants (e.g. Pharmaceutical Solutions[5]) have entered the CRO-space also.

However, despite the wide-ranging nature of clinical research in New Zealand, as mentioned in Section 1, there has been limited research on the benefits of clinical trial participation in New Zealand (Lockhart et al. 2013). The literature reveals a range of benefits from clinical trials to different groups of people and to the health system as a whole.

## Benefits for trial participants

There is evidence of better clinical outcomes for patients when they enrol in a clinical trial as opposed to those from standard care (Murphy 2012). This is due to the extensive protocol-driven medical monitoring and assessment (usually including laboratory and in some cases radiological assessments) paid for by the trial Sponsor that participants in studies receive during the trial that is over and above usual clinical practice. Patients enrolled in the trials have their expenses associated with trial participation covered, and in some cases (for example Phase I research or studies which involve unusually lengthy or onerous study assessments) may also receive payment for participation. It is important to note that all payments for participation are reviewed as part of the ethical approval process

2 https://www.syneoshealth.com/our-office-locations

3 https://www.iqvia.com/locations/australia-and-new-zealand

4 https://www.covance.com/industry-solutions/drug-development/by-geography/asia-pacific/new-zealand.html

5 https://pharmasols.com/about-us

for the study to ensure that they are set at an appropriate level so as to not unethically induce trial participation.

Benefits to trial participants also come in the form of saved Quality Adjusted Life Years (QALYs) or Disability Adjusted Life Years (DALYs). For example, in Ireland clinical trials can lead to savings in QALYs worth between €0.28 million and €0.72 million per trial (DKM Consultants Ltd 2016) and 8,326 DALYs in Thailand (Deloitte Access Economics 2016).[6]

## Benefits for DHBs, Primary Care Providers, and Health Professionals

The benefits for District Health Boards (DHBs) and Primary Care Providers include access to therapies that are unavailable in New Zealand as they are not registered and/or funded here, and also the potential to present alternatives to standard care for patients with diseases that have proved refractory to standard treatments or for which no standard treatments are yet available. DHBs and Primary Care Providers gain access to trial interventions at no cost to themselves or their patients and in addition to the provision of the trial interventions, they generally receive payment or grant-based funding for their participation in the trials.[7] Receipt of this clinical trial funding can also enhance the capacity and capability within the health system. The funding can allow staff training, which in turn can increase human capital in the clinical trial sector. Research participation can lead to greater exposure to the latest innovations in clinical practice and improve knowledge translation of evidence-based improvements in clinical care thus allowing the health system to increase efficiency in delivering optimal clinical outcomes for the population (MTPConnect and L.E.K. 2017). The ability for investigators to participate in clinical trial research aids in recruiting and retaining high calibre staff (Fassbender 2017a). Additionally, clinical trial funding can contribute to better infrastructure at clinical sites (Fassbender 2017b), which can lead to further R&D in the health care sector.

Researchers also argue that there are cost savings due to clinical centres removing patients out of the public system for the duration of the trial (Murphy 2012). For example, in New Zealand, Middlemore Clinical Trials (MMCT) have an estimated cost savings of $1 million in 2018 (Middlemore Clinical Trials 2018). In the UK, it was estimated that clinical trials can create savings of £16 million per year or £4,700–£5,780 per patient for their National Health System (NHS) (KPMG 2016). A study of the Irish clinical sector estimated savings to their Health System Executive (HSE) of €6.5 million per annum (DKM Consultants Ltd 2016).[8]

## Benefits for research institutes and their students – including universities and hospitals

As well as providing revenue, there are benefits for both students, researchers and institutions.

For post-graduate students, clinical trials provide the opportunity of being involved with applied research. Research associated with trials may provide suitable topics for research masters and PhDs.

[6] We do not attempt to quantify these for the New Zealand clinical trial sector as these international estimates are derived from specific clinical trials for specific diseases.

[7] Based on a discussion with Dr Ian Town.

[8] We do not attempt to quantify these for the New Zealand clinical trial sector as these international estimates are derived from specific clinical trials for specific diseases.



The growth in the CRO-sector provides alternative opportunities outside of the academic and public health sectors within New Zealand for graduates of biomedical and life sciences. These opportunities pay better than the average income in New Zealand (Seek n.d.; Statistics New Zealand n.d.) and may stimulate study in these fields and promote the retention of these graduates within New Zealand.

Also, there are degree programmes offered in clinical research. For example, Victoria University of Wellington offers masters degrees and postgraduate diplomas in clinical research which include applied clinical research.

The quality and quantity of publications and citations are one of the factors underpinning the PBRF (Performance-based Research Fund) funding for universities, as well as the reputation of researchers and institutions. These may be able to be built around clinical trials.

# 4 Results

In this section we present the results of the direct, indirect and total economic contributions by SCOTT trials in New Zealand. The results are presented for years 2013 to 2018. Further details on the data sources and limitations, the economic contribution framework and detailed definitions can be found in Section 2 and Appendix A.

Table 1 below shows the number of clinical trials and participants in those trials conducted between 2013 and 2018.

### Table 1 Number of clinical trials and participants

2013 to 2018

| Year | Number of studies | Number of participants |
|---|---|---|
| 2013 | 129 | 5653 |
| 2014 | 126 | 3676 |
| 2015 | 156 | 6785 |
| 2016 | 100 | 4120 |
| 2017 | 119 | 3729 |
| 2018 | 147 | 3811 |

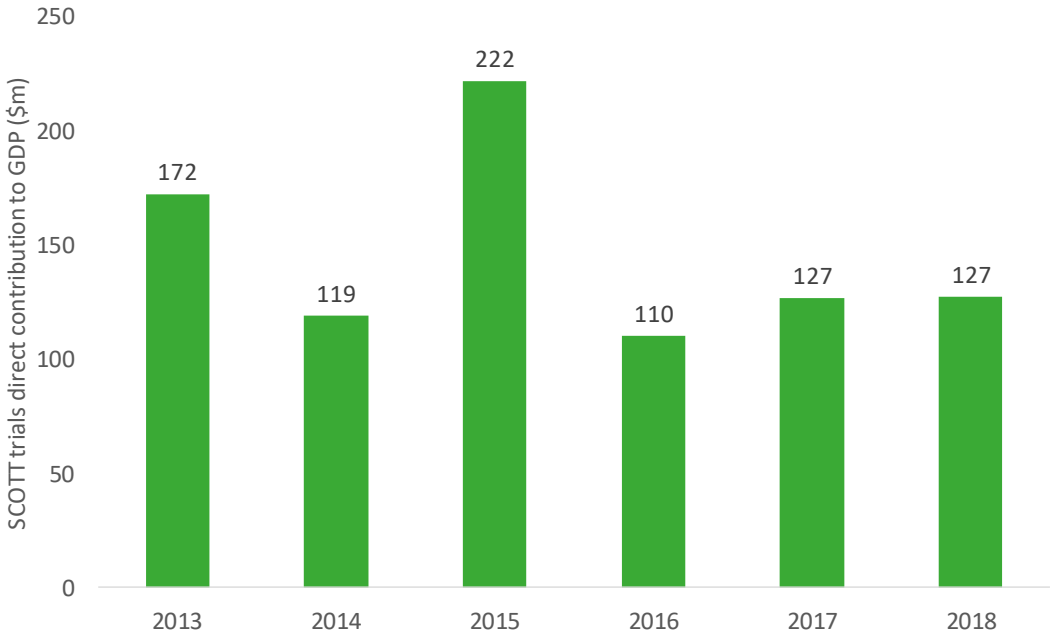
Source: NZIER, Medicines New Zealand

## 4.1 Direct contribution

The direct contribution represents the contribution to GDP (gross domestic product). SCOTT trials directly accounted for **$127.4 million of New Zealand's total GDP in 2018**. Figure 1 below shows the direct contribution pattern since 2013.

## Figure 1 Contribution to GDP has been relatively flat[9]

NZ$ millions




Source: NZIER

The direct contributions for 2013 and more so for 2015 stand out as unusual years. In the case of 2015 the highest number of trials is recorded for the period reviewed (156 trials) and in the case of 2013 there was the third highest number of trials (129 trials) over the 6 years studied but the average number of participants scheduled per trial was higher than in other years (about 44 patients per trial in 2013).

Investigating this further, we break down the number of trials and participants by phase in Table 2 and Table 3 below, respectively.

## Table 2 Number of clinical trials by phase

2013 to 2018

| Year | Phase I & GB* | Phase II | Phase III | Phase IV | Total |
|---|---|---|---|---|---|
| 2013 | 15 | 39 | 72 | 3 | 129 |
| 2014 | 25 | 35 | 65 | 1 | 126 |
| 2015 | 37 | 39 | 78 | 2 | 156 |
| 2016 | 29 | 24 | 41 | 6 | 100 |
| 2017 | 36 | 25 | 55 | 3 | 119 |
| 2018 | 56 | 35 | 54 | 2 | 147 |

*GB = Generic/Bioequivalence trials (Medsafe's dataset included 11 GB trials in the 2018 dataset and 2 in 2017).
Source: NZIER

[9] All values are in 2018 dollars.

## Table 3 Number of participants by phase

2013 to 2018

| Year | Phase I & GB* | Phase II | Phase III | Phase IV | Total |
|---|---|---|---|---|---|
| 2013 | 836 | 1285 | 3024 | 508 | 5653 |
| 2014 | 601 | 606 | 2419 | 50 | 3676 |
| 2015 | 1503 | 848 | 4432 | 2 | 6785 |
| 2016 | 1189 | 495 | 1152 | 1284 | 4120 |
| 2017 | 1678 | 717 | 1244 | 90 | 3729 |
| 2018 | 1564 | 858 | 1373 | 16 | 3811 |

*GB = Generic/Bioequivalence trials

Source: NZIER

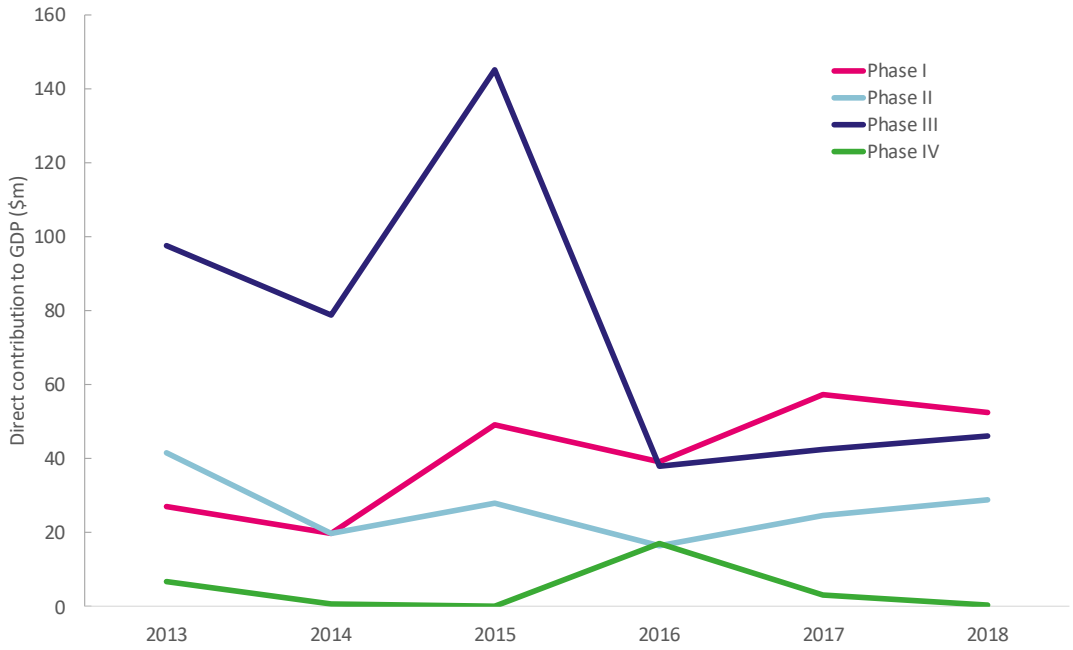
The higher value for the average number of participants in 2013 will be associated in part with 2013 having the highest proportion of later phase trials (75 out of 129) as later phase trials (i.e. Phase III and IV studies) have more participants than earlier phase trials. Putting aside these outliers, the direct contribution has been relatively flat over the past few years.

The contribution to GDP broken down by phases is presented in Figure 2 on the next page. Phases I to III are more resource intensive than Phase IV (Deloitte Access Economics 2016) and in our SCOTT trials dataset there are significantly more Phase I to III trials than Phase IV trials (as most Phase IV trials are not submitted to the SCOTT).[10] Both these effects lead to a greater direct contribution to GDP from Phase I to III trials than Phase IV trials.

[10] More details in Section 2.

### Figure 2 Contribution to GDP has primarily been from Phase III trials[11]

NZ$ millions




Source: NZIER

It appears that the peaks in direct contribution to GDP in 2013 and 2015 are primarily due to the contribution from Phase III trials. This is due to the relatively large number of Phase III trials and the number of patients enrolled in them. Between 2013 and 2015 there was a general trend of a higher number of Phase III trials. However, between 2016 and 2018, the number of Phase III trials has declined considerably but, there is an increase in Phase I trials. This suggests that in recent years there is a shift away from Phase III trials and a shift towards Phase I trials.

## 4.2 The value of Phase IV clinical trials could be underestimated

It is likely that our estimates based on the SCOTT trials dataset are undervaluing the overall economic contribution of Phase IV trials in New Zealand. Phase IV research conducted in New Zealand includes research conducted by non-commercial and academic organisations, funded by the HRC, charitable sources and international research collaborations. These studies include large comparative effectiveness studies of registered medicines for common health conditions. Studies of this type which originate in New Zealand could be registered with the ANZCTR, but a number of international research groups (including Australian research groups) not infrequently use international registries such as ClinicalTrials.gov.

We also cannot accurately assess the full number of all post-marketing surveillance (Phase IV) clinical trials sponsored by commercial sponsors that are taking place in New Zealand, and not just those trials which have been submitted to SCOTT. Commercial sponsors provide revenue earned through fees earnt and free access to modern medicines approved as therapeutic in at least one regulatory jurisdiction (Middlemore Clinical Trials n.d.).

[11] All values are in 2018 dollars.

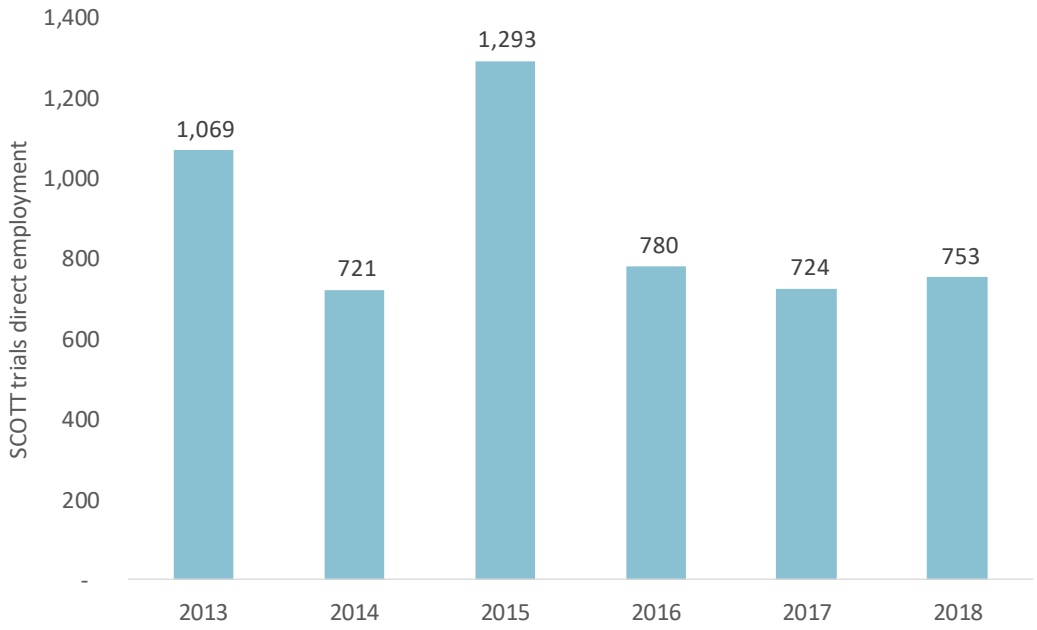
As discussed in Section 2, analysis of registry data can be problematic. However, in order to gain further information about the size of the overall Phase IV research sector in relation to overall medicines-related clinical research activity and the proportion of that sector relating to trials of modern medicines, a review of Phase IV trial activity was undertaken using ANZCTR data (ANZCTR n.d.). The ANZCTR reported in 2018 (Australian New Zealand Clinical Trials Registry 2018) that a "*total of 116 phase 4 studies have been registered between 2006 and 2015, accounting for 10 per cent of drug trials overall and a relatively consistent 6-12 per cent each year*". When we produced reports from the registry of trials registered to date (13 February 2020), including those trials designated as Phase IV and trials designated as Phase III/IV in the registry, we found 142 trials, which suggests that the level of Phase IV activity has been relatively constant. However, after a line-by-line review of these records we found that only 39 of the 142 trials (27%) could be considered to be therapeutic efficacy trials of modern medicines (that is trials involving a medicine that had not been registered in New Zealand more than a decade prior to trial registration). The majority of these trials were sponsored by academic or non-commercial sponsors.

We also reviewed 2018 data for Phase IV clinical trials using the registry ClinicalTrials.gov (ClinicalTrials.gov n.d.) and compared New Zealand with a number of other countries. Data for 2018 would suggest that the Phase IV trial activity in New Zealand as a proportion of overall trial activity is comparable with that of Ireland (1.4% vs 1.6%), is somewhat less than Australia, Hungary and the United Kingdom (2.2%, 2.7% and 4.9%, respectively) and notably less than the US (12.0%) and Thailand (12.9%). As this is a US registry commonly used for the registration of multinational trials by pharmaceutical companies, the results obtained from this registry may provide a more accurate estimate of what proportion of clinical trial activity in New Zealand could be attributable to commercial Phase IV trials of modern medicines than ANZCTR data. These proportionate results from ClinicalTrials.gov are also notably closer than the findings of the ANZCTR to the proportion of Phase IV and Early Access Protocol trials included in the SCOTT dataset results for 2013–2018.

## 4.3 Direct employment

Direct employment refers to employment in SCOTT trials, which directly contributes to GDP through labour income. The clinical trials sector directly employed 753 staff in 2018. Figure 3 below shows the direct employment pattern since 2013.

## Figure 3 SCOTT trials' employment has been roughly constant




Source: NZIER

Again, ignoring the outlier values in 2013 and 2015, we see a roughly constant pattern in direct employment.

Table 4 below shows SCOTT trials' direct employment by phase. As discussed above, due to greater number of Phase I to III trials in our dataset and greater resource requirements for these trials, there is greater employment in Phase I to III trials than in Phase IV trials.

## Table 4 Direct employment by phase

2013 to 2018

| Year | Phases I – III | Phase IV | Total* |
|---|---|---|---|
| 2013 | 977 | 92 | **1,069** |
| 2014 | 712 | 9 | **721** |
| 2015 | 1,292 | 1 | **1,293** |
| 2016 | 548 | 232 | **780** |
| 2017 | 707 | 17 | **724** |
| 2018 | 750 | 3 | **753** |

* Numbers may not add up due to rounding.

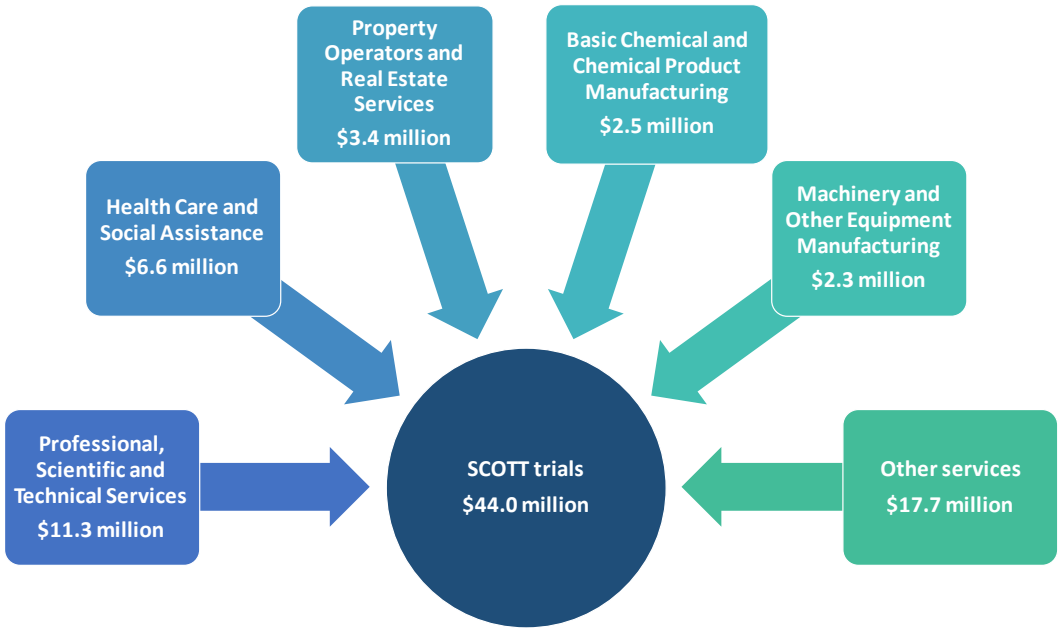
Source: NZIER

## 4.4 Indirect contribution

As well as its direct impacts, the SCOTT trials also play an important role in supporting activity in other parts of the New Zealand economy by purchasing supplies from them. This is known as an indirect contribution. The SCOTT trials sector purchased $44.0 million of inputs from supporting sectors in 2018.

Figure 4 below shows the purchases made by SCOTT trials to support its operations in 2018.

### Figure 4 SCOTT trials draw on inputs from a wide range of supporting industries[12]



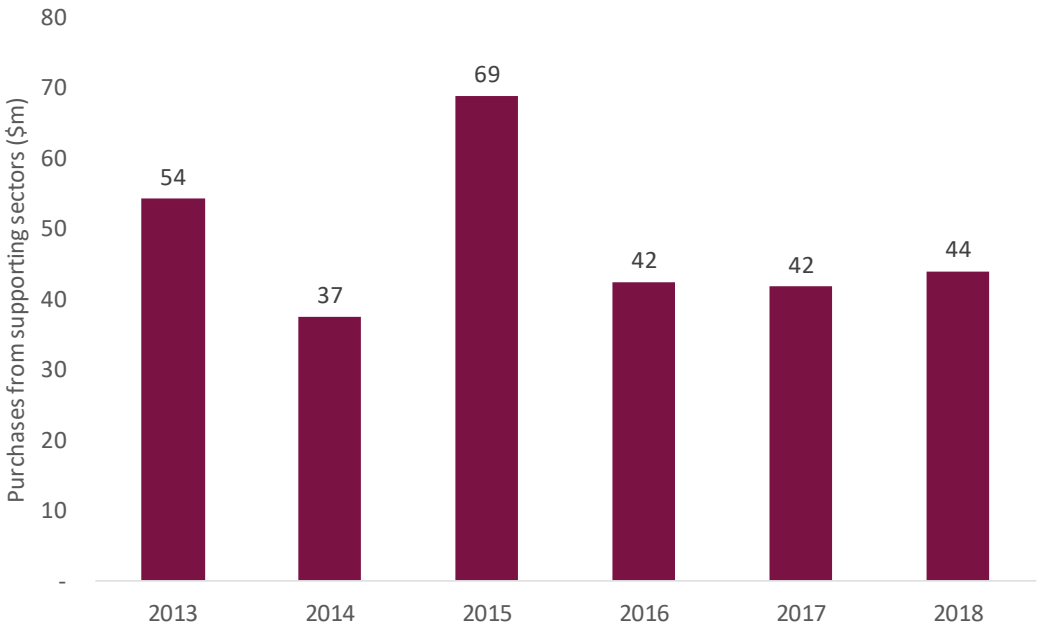

Source: NZIER, Statistics New Zealand

Like the direct contribution, the indirect contribution of SCOTT trials has also remained relatively flat, after discarding the two possible outliers – years 2013 and 2015 (Figure 5 below). The methodology for determining the indirect contribution is detailed in Appendix B.2.

[12] Numbers may not add up due to rounding.

## Figure 5 SCOTT trials' purchases of inputs have remained relatively flat

2018; NZ$ millions




Source: NZIER, Statistics New Zealand

The indirect contribution is broken down by phases in Table 5 below. As with the direct contribution, Phases I to III trials draw a larger portion of inputs from supporting sectors compared to Phase IV trials.

## Table 5 Indirect contribution by phase

2018 dollars; NZ$ millions

| Year | Phases I – III | Phase IV | Total* |
|---|---|---|---|
| 2013 | $52.2 | $2.06 | **$54.3** |
| 2014 | $37.2 | $0.21 | **$37.4** |
| 2015 | $68.8 | $0.01 | **$68.8** |
| 2016 | $35.9 | $6.51 | **$42.4** |
| 2017 | $40.7 | $1.01 | **$41.7** |
| 2018 | $43.9 | $0.07 | **$44.0** |

* Numbers may not add up due to rounding.

Source: NZIER, Statistics New Zealand

## 4.5 Indirect employment

Employment in the supporting industries supported in part due to the operation of the SCOTT trials is known as indirect employment. The clinical trials sector supported 222 jobs in supplying sectors (Table 6 below).

### Table 6 Supporting sector jobs

2018

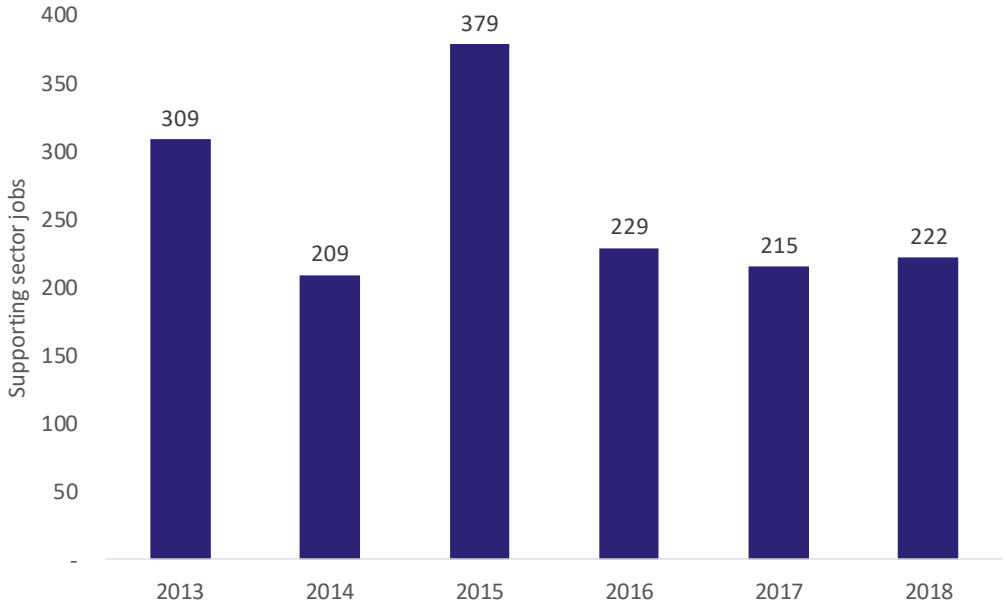
| Sector | Jobs |
|---|---|
| Health Care and Social Assistance | 60 |
| Professional, Scientific and Technical Services | 56 |
| Administrative and Supportive Services | 24 |
| Education and Training | 13 |
| Accommodation and Food Services | 10 |
| Other Services | 59 |
| **Total*** | **222** |

* Numbers may not add up due to rounding.

Source: NZIER, Statistics New Zealand

Following the same reasoning as the pattern in indirect contribution, supporting sector jobs have also remained relatively consistent (Figure 6 below).

### Figure 6 Supporting sector jobs have remained relatively consistent




Source: NZIER, Statistics New Zealand

Table 7 below shows SCOTT trials' indirect employment by phase. Similar to direct employment, there were a greater number of jobs supported by Phase I to III trials than Phase IV trials.

### Table 7 Indirect employment by phase

| Year | Phases I – III | Phase IV | Total* |
|---|---|---|---|
| 2013 | 282 | 27 | **309** |
| 2014 | 207 | 3 | **209** |
| 2015 | 378 | 1 | **379** |
| 2016 | 161 | 68 | **229** |
| 2017 | 210 | 5 | **215** |
| 2018 | 221 | 1 | **222** |

* Numbers may not add up due to rounding.

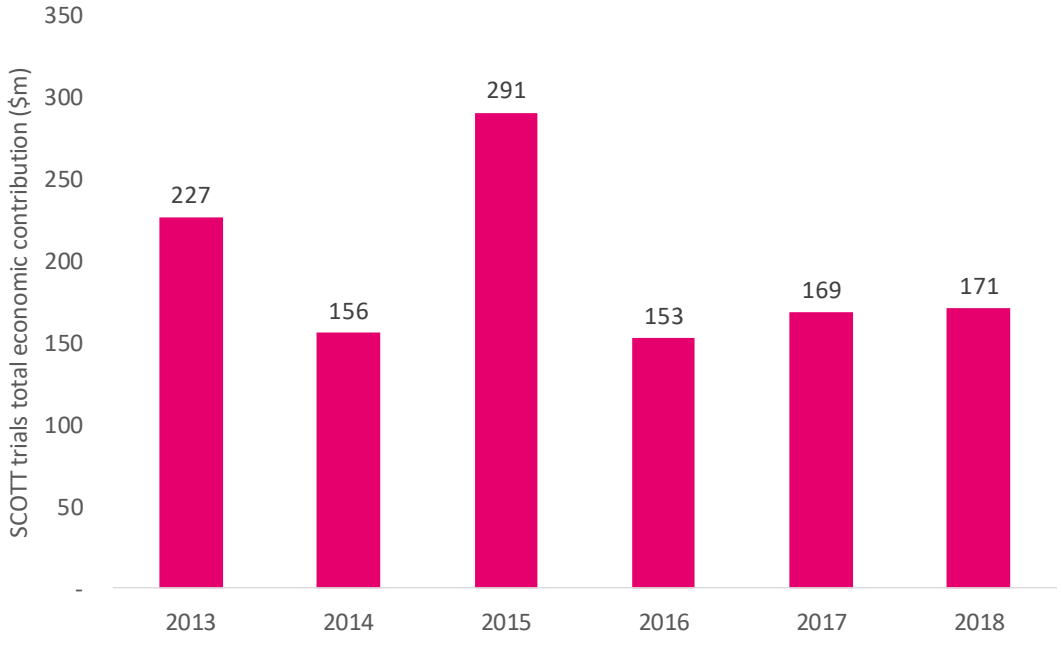
Source: NZIER, Statistics New Zealand

## 4.6 Total economic contribution

The total economic contribution is the sum of the direct and indirect contributions to the economy. The total economic contribution of SCOTT trials was $171.4 million in 2018. The two outliers (years 2013 and 2015) in the direct and indirect contribution flow to the total contribution meaning the total contribution has also remained relatively consistent (Figure 7 below).

### Figure 7 Total economic contribution has remained relatively flat

2018; NZ$ millions




Source: NZIER

As a comparison, the SCOTT trials' total contribution was roughly 13% of the contribution from the scientific research industry, over 1.5 times the contribution from mushroom

growing industry ($105 million) and 14 times the contribution of olive growing industry ($12 million) in 2018 (Statistics New Zealand n.d.).[13]

The total economic contribution, broken down by phases, is presented in Table 8 below.

### Table 8 Total economic contribution by phase

2018 dollars; NZ$ millions

| Year | Phases I – III | Phase IV | Total* |
|---|---|---|---|
| 2013 | $217.9 | $8.61 | **$226.5** |
| 2014 | $155.4 | $0.86 | **$156.3** |
| 2015 | $290.6 | $0.03 | **$290.6** |
| 2016 | $129.3 | $23.41 | **$152.7** |
| 2017 | $164.7 | $4.07 | **$168.7** |
| 2018 | $171.1 | $0.29 | **$171.4** |

* Numbers may not add up due to rounding.

Source: NZIER, Statistics New Zealand

The total contribution by SCOTT trials can also be broken down by the conditions these trials are investigating for treatments or preventions.

Investigations into treating and preventing 'Infections' and diseases associated with infection (e.g. Hepatitis B and C) had the greatest contribution to the economy. Table 9 below shows the aggregate contribution of the top 10 conditions investigated between 2013 and 2018 (inclusive).

### Table 9 Contribution by condition category

2013-2018; NZ$ millions

| Condition category | Total contribution |
|---|---|
| Infection | $247.8 |
| Cancer | $213.7 |
| Reproductive health and childbirth | $78.2 |
| Inflammatory & Immune System | $66.2 |
| Metabolic & endocrine | $65.8 |
| Oral & Gastrointestinal | $61.2 |
| Mental Health | $59.5 |
| Cardiovascular | $57.9 |
| Respiratory | $54.5 |
| Public Health | $42.2 |
| Other conditions | $219.2 |

Source: NZIER, Medicines New Zealand

[13] We also used NZIER's in-house model of the New Zealand economy for these calculations.



## 4.7 How does New Zealand compare with other countries?

Even though our economic contribution estimates are conservative, SCOTT trials (our clinical trials proxy) in New Zealand appear to be contributing more to GDP relative to its population than those being carried out in Hungary, Ireland and Thailand, but less than Australia and United Kingdom (UK) (Table 10 below).[14]

### Table 10 Direct contribution per person

Years vary between 2014 and 2018; NZ$

| Country | Direct contribution per person |
|---|---|
| UK | $85 |
| Australia | $52 |
| **New Zealand** | **$26** |
| Hungary | $19 |
| Thailand | $4 |
| Ireland | $3 |

Source: NZIER, KPMG 2016; Office for National Statistics n.d.; Deloitte Access Economics 2016; The World Bank n.d.; n.d.; n.d.; n.d.; n.d.; DKM Consultants Ltd 2016; Central Statistics Office n.d.; Kaló et al. 2014; MTPConnect and L.E.K. 2017; Australian Bureau of Statistics 2015; Reserve Bank of New Zealand n.d.; Statistics New Zealand n.d.

These countries were chosen as points of comparison based on data availability.

SCOTT trials' direct contribution to GDP as a share of its own GDP is greater than that of Ireland, but slightly less than that of other countries in our comparison (Table 11 below). This could be due to our estimates being conservative and not capturing New Zealand's entire clinical trials sector.

### Table 11 Direct contribution of clinical trial sector as % of own country's GDP[15]

Years vary between 2014 and 2018

| Country | % of GDP |
|---|---|
| UK | 0.130% |
| Hungary | 0.119% |
| Australia | 0.062% |
| Thailand | 0.050% |
| **New Zealand** | **0.044%** |
| Ireland | 0.004% |

Source: NZIER, (KPMG 2016; Office for National Statistics n.d.; Deloitte Access Economics 2016; The World Bank n.d.; n.d.; n.d.; n.d.; n.d.; DKM Consultants Ltd 2016; Central Statistics Office n.d.; Kaló et al. 2014; MTPConnect and L.E.K. 2017; Australian Bureau of Statistics 2015; Reserve Bank of New Zealand n.d.; Statistics New Zealand n.d.)

[14] Refer to Appendix C on the reasons for comparing direct contribution only to GDP between countries.

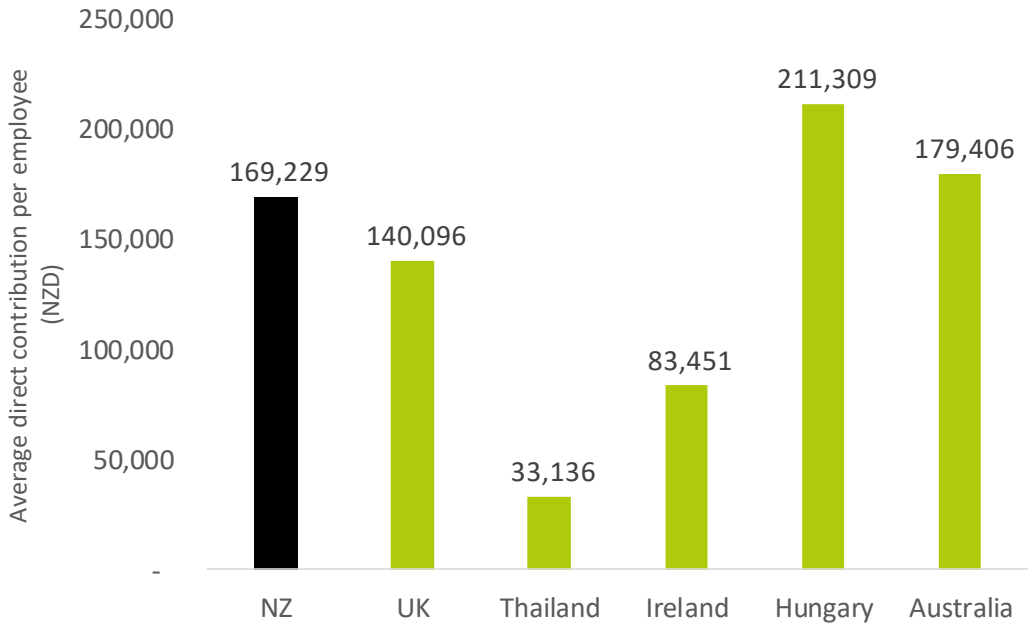
[15] For New Zealand this represents SCOTT trials only.



**The average direct contribution per employee for SCOTT trials in New Zealand is $169,230**, which is greater than the contribution per employee of the clinical trials' sectors in the UK, Ireland and Thailand, but less than that of Hungary and Australia (Figure 8 below). The reasons for differences between the countries are unclear but it could be due to a combination of differences in wage rates, cost structures, efficiencies or administration arrangements.

### Figure 8 SCOTT trials contribute more per employee than other comparable countries

NZ$




Source: NZIER

## 5 So, what next?

We have seen a relatively consistent contribution of SCOTT trials to the economy over the past six years along with numerous benefits to the overall health system such as improved staff recruitment/retention, knowledge translation leading to improvements in clinical practice, cost savings to the system and health outcome benefits to patients who are trial participants.

But, having a narrowed scope of focus on pharmaceutical SCOTT trials exclusively suggests better quality data concerning clinical trial activity that is inclusive of the wider clinical trial sector is needed to provide a complete picture. Other clinical trial registries are plagued with their own errors such as missing data or double/triple counting entries. Additionally, there is a missing network that incorporates resources from both the public and private sectors where activity in one of these sectors benefits the other. This network can lead to

better clinical trial infrastructure and enhance New Zealand's international reputation and that of its researchers (MTPConnect and L.E.K. 2017).[16]

Our specific recommendations for improvement include:

- Better promotion of transparency of reporting trial results.
- Clinical trial data management in accordance with Principles and Protocols as established by Statistics New Zealand (Statistics New Zealand 2012).
- The development of centralised repository to collect data on clinical trial activity across the wider sector.
- Regular publication of funding to inform stakeholders of the benefits and opportunity afforded due to non-commercial clinical trial research in New Zealand.

[16] Based on a discussion with Dr Ian Town.

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# Appendix A Definitions

Clinical trials can be broken down into six phases of testing (Australian New Zealand Clinical Trials Registry 2018; Medsafe 2013):

## Phase I

This phase tests a new biomedical intervention to establish safety and optimal dose of the new intervention. These studies follow on from pre-clinical investigations of the investigational product, i.e. in vitro[17] and in vivo[18] laboratory testing and attempt to establish basic safety, optimal dose and pharmacokinetic[19] profile in humans of the investigational product. Usually 'healthy volunteers', i.e. not the patient-group of potential interest for the test agent are involved.[20] In healthy volunteer trials, there is no therapeutic benefit for the participants, and they are generally paid to participate. These trials will often involve in-patient stays, and intense regimens of clinical assessments. In New Zealand, they are generally run in purpose-built private facilities. Typical number of trial participants are between 20 and 100.

## Phase II

These are generally the first trials performed on the patient group of interest with a focus on establishing the effect the drug has on the body and further dose-finding work and are generally placebo-controlled. Usually the entry criteria for these trials are restrictive, so do not allow for generalisability of study findings to the wider-patient group at which the investigational product is aimed. The treatment period of these trials is typically no longer than six months in duration in the investigation of treatments for chronic conditions. Due to the lack of evidence to support the efficacy and tolerability of the investigational product being tested, and the generally short duration of the trial, most studies in Phase II cannot be considered potentially therapeutic for trial participants. Typical number of trial participants are between 100 and 300.

## Phase III

This phase tests the efficacy and safety of an investigational product by comparing the investigational product to a control treatment which is generally either "standard of care" treatment (i.e. other medicines or treatments normally used in patients with the condition of interest) or a placebo control (or in some cases both control options). The trial 'treatment' period for studies of treatments for chronic conditions is generally a minimum of 12 months and is often longer for studies assessing mortality as a pre-specified outcome measure.[21] Participants are clinically followed regularly, e.g. follow-ups once a month study screening. Follow-up will include clinical assessments that these participants may not otherwise be having. Greater evidence indicative of treatment efficacy is required to commence a Phase III study and these studies may be considered to have greater therapeutic potential. Trial participant numbers vary greatly according to the health

17 Performed outside a living organism, e.g. in a test tube.

18 Performed within a living organism.

19 Study of what happens to the living organism when presented with the investigational product, i.e. absorption, distribution, metabolism and excretion/elimination from the living organism.

20 Unless the trial involves known high risk products for use in serious illness such as chemotherapy agents in cancer patients.

21 Or longer than 12 months in disease areas where 'survival'/ freedom from significant life-threatening events are primary or secondary outcome measures e.g. cardiovascular and oncology studies.

condition that the investigational product is being tested in but are typically between 300 and 3,000 (or more).

### Phase IV

Phase IV studies are trials of medicines that have been approved (registered or authorised) by at least one Regulatory Authority/Agency. These studies are sometimes described as 'post-marketing studies' as the purpose of the studies is to monitor the effectiveness and safety concerns in the public after the investigational product has been approved for sale. Monitoring is done over long periods of time and can also be used to investigate the potential use of the investigational product in conjunction with other investigational products or under different conditions (including variation in patient group characteristics).

### Generic/bioequivalence trials

These trials compare the pharmacokinetic (PK) profiles of new 'generic' medicines with that of the established originally patented 'branded' medicine (i.e. the innovator medicine). A generic medicine contains the same active ingredient in the same quantity as the innovator medicine and also has to be manufactured according to international standards for Good Manufacturing Practice (Medsafe 2013). However, they may have different inactive ingredients such as preservatives or other 'filler' chemicals.

As the clinical effect (and tolerability profile) of the active ingredients has been demonstrated in previous research with the innovator product, the purpose of these types of trials is to demonstrate whether the generic and innovator medicines have comparable bioavailability in the human body.

These trials are generally conducted in healthy volunteers. Operationally they have some similarity to Phase I studies in terms of clinical procedures undertaken i.e. the collection of samples from healthy volunteers for the purpose of assessing PK study endpoints. However, as they are not "first in humans" studies of a novel medicinal substance, their lower risk profile means that the conduct of these protocols may be clinically less intensive. These trials are generally also viewed as less experimental from a regulatory perspective and provided they meet specific criteria, undergo an abbreviated approval process operated by Medsafe (Ministry of Health 2018). The dataset provided by Medsafe included records for 13 trials categorised as generic/bioequivalence studies (including 11 from 2018). Given their similarities of protocol design (pharmacokinetic assessment) and participant group (healthy volunteers) to Phase I studies, and the low numbers of these trials included in the dataset, a decision was made that it was most appropriate to include them in the Phase I study category estimates rather than treating them as a separate category for the purpose of our economic analysis.

### Early Access Protocol trials

These trials are studies of unregistered medicines. They gather data about the long-term effects (tolerability/safety) of the medicine, whilst providing on-going access of the medicine to those participants in the Phase III trials that are likely to benefit from it. These trials are a follow-on from the efficacy establishing Phase III trials and are often referred to as "open-label extension studies".

They may run for years however, the intensity of the clinical assessment and procedures undertaken from these trials and thus, **the per-patient fees are more reflective of that of**



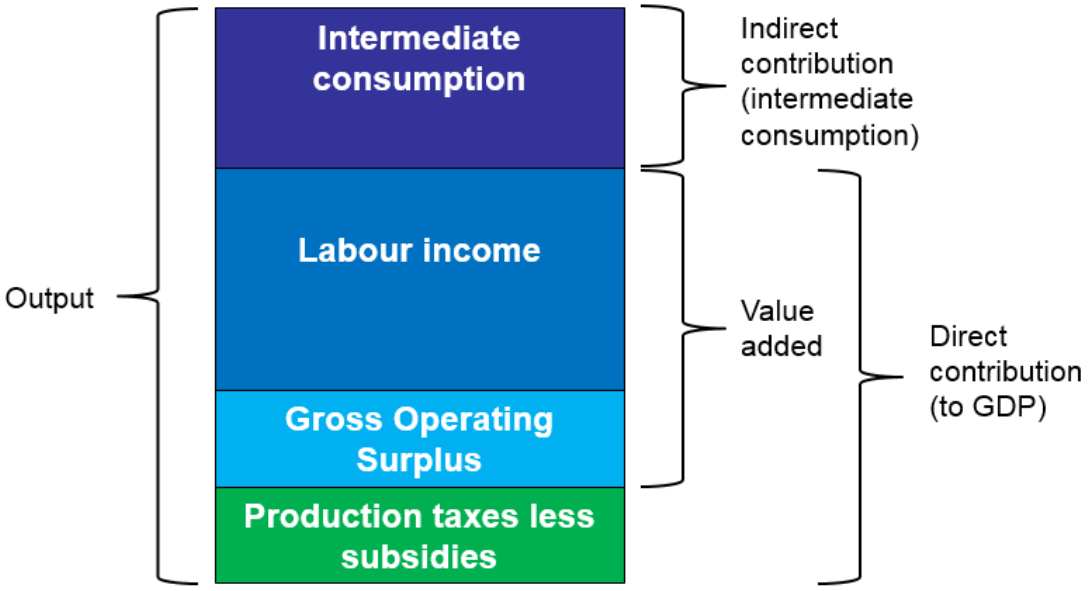
**Phase IV studies** than earlier phase studies because clinical follow-up appointments will be less frequent and/or shorter in duration.

Accordingly, for the purpose of our economic analysis these trials were included in the Phase IV category estimates.

# Appendix B Economic contribution framework

The economic contribution framework is presented in Figure 9 below.

**Figure 9 Economic contribution framework**




Source: NZIER

The method to derive the direct and indirect contributions described in Appendixes B.1 and B.2 below both reference Figure 9 above.

## B.1 Direct contribution

A sector's direct economic contribution to GDP is its value-added plus production taxes[22] less subsidies. For simplicity, we ignore the production taxes and subsidies. Thus, a sector's direct contribution is its *value-added*. This measures the value of its output, i.e. goods and services generated through its inputs, i.e. capital and labour. The sum of value added across all sectors of the economy gives the economy's GDP. The value added is the sum of:

- **Gross Operating Surplus:** This is the income generated through the sector's capital inputs, generally measured as the earnings before interest, tax, depreciation and amortisation (EBITDA).
- **Labour income:** This is the value created by a sector through its labour input. It is measured as income to labour.

A literature review of international studies shows that it is fair to assume that clinical research activity, both within the public sector, and within private sector R&D teams, do not make profit. This means the direct contribution to GDP would be approximated on labour income alone (DKM Consultants Ltd 2016; KPMG 2016; 2019). However, SCOTT trials are primarily reflective of commercially sponsored Phase I to III trials, which are conducted

[22] Inclusive of company taxes and employment taxes. Note: EBITDA includes return to capital before tax, so company tax is not included otherwise this would double count the tax.

in New Zealand on a for-profit basis. Therefore, direct contribution to GDP will be approximated on labour income *and* gross operating surplus.

### B.1.1 Labour income

**Clinical trial staff = number of participants x clinical trial staff per participant**
The Middlemore Clinical Trials (MMCT) Annual Report (Middlemore Clinical Trials 2018) presented the number of participants in commercial clinical trials conducted in Middlemore Hospital along with the number of research nurses employed by MMCT conducting those trials. Additionally, employees of the Counties Manukau District Health Board including research nurses in other departments, principal investigators (PIs), phlebotomists, research pharmacists and academics are also involved in conducting clinical trials. A further discussion with MMCT gave us an indication on these numbers. Hence, we use the following:

- 514 patients enrolled
- 24 MMCT research nurses
- 4 research nurses in paediatrics, 2 research nurses in intensive care units (ICU) and 2 research nurses in the emergency room (ER).
- 58 PIs and sub investigators
- 1 phlebotomist
- 1 research pharmacist.

These numbers provide us with a clinical trial staff per participant ratio. Multiplying this ratio by the number of participants scheduled to participate (Section 2) gave us an estimate of the total clinical trial staff in SCOTT trials.

We estimate the salary per clinical trial employee using the Multi-Employer Collective Agreements (MECA). The salaries are presented in Table 12 below:

**Table 12 Clinical trial staff salaries**

| Role | Annual salary |
|---|---|
| Research nurses[23] | $81,322 |
| PIs and sub PIs[24] | $149,365 |
| Phlebotomist[25] | $61,854 |
| Research pharmacist[26] | $61,854 |

Source: Association of Salaried Medical Specialists 2017; New Zealand Nurses Organisation 2018; Public Service Association 2018

Labour income is finally determined by multiplying the salary per clinical trial employee by the estimated number of clinical trial staff.

[23] Intermediate step of Grade 2 Senior Nurses.

[24] We assume doctors selected to be Principal Investigators will have at least an intermediate level of professional experience. So, we are basing PI salaries on step 7 of the salary grade for Medical and Dental Officers.

[25] Step 2 (Intermediate) salary grade.

[26] Step 2 (intermediate) salary grade.

**Medical research workforce**

The approach described above relies on the clinical trial staff structure of one organisation being applied to the clinical trial industry. If we were to take an industry-wide approach, we would be reliant on employee numbers and wages provided by Statistics New Zealand's Linked Employer Employee Dataset (LEED), which is publicly available. As mentioned above, clinical trial staff can belong to various departments. These departments would fall under the following Australian and New Zealand Standard Industrial Classification (ANZSIC) medical research industries (KPMG 2018):

- Scientific Research Services
- Hospital
- Medical Services
- Pathology and Diagnostic Imaging
- Higher Education.

However, due to the confidentiality restrictions, it was not possible to determine the proportion of these industries that account for clinical trials specifically. While this approach was not useful for determining the labour income component of the direct contribution, the medical research industries ANZSIC industries were useful for determining indirect contribution discussed below (Appendix B.2).

### B.1.2 Gross operating surplus

Ideally, we would determine gross operating surplus by calculating EBITDA using financial statements of each organisation that conducted SCOTT trials. However, this level of granularity was not available to us. A study conducted on the clinical trials sector in Thailand provides value-added by the clinical trials sector and its labour income (Deloitte Access Economics 2016). These two values suggest labour income accounts for approximately 64% of value-added, which means the remaining 36% accounts for gross operating surplus. We use these proportions in our analysis to determine the gross operating surplus of SCOTT trials.

### B.1.3 Phase IV requires fewer resources

Phases I to III are more resource intensive on a per-participant basis in terms of clinical assessments required to conduct the protocol and are conducted in larger numbers than Phase IV trials. Phase IV trials are estimated to require 40% of the resources required for phases I to III (Deloitte Access Economics 2016). Hence, we assume that Phase IV trials directly contribute 40% of the direct contribution of Phases I to III to the New Zealand economy.

## B.2 Indirect contribution

The indirect contribution of a sector measures the demand for goods and services from other sectors to support its operations. This is also known as *intermediate consumption* and refers to the intermediate consumption component in Figure 9 above.

We estimate the indirect contribution using the Statistics New Zealand's input-output (IO) tables (Statistics New Zealand n.d.). These tables split the New Zealand economy into 106 industries and 201 commodities. As discussed in Appendix B.1, clinical trials fall under five



ANZSIC industries. Using the IO tables, we established the commodities that these five industries purchased to support their operations and apportioned it based on the SCOTT trials employment as a share of the total employment in these five industries. Finally, we determined the employment in these supporting five industries that supported the clinical trials sector based on the value of commodities purchased as a share of the total output of the industries that produced those commodities. This is referred to as indirect employment.



# Appendix C Why only compare direct contribution?

We only compare direct contribution between countries because the international literature containing direct contribution of clinical trials on other countries uses a similar approach to the one mentioned in Appendix B.1. The indirect contribution for other countries was determined using a different approach to the one mentioned in Appendix B.2. Specifically, other countries have used 'multiplier' effects to determine indirect contribution. NZIER does not use 'multiplier' studies because they over-state economic impact estimates. The 'multiplier' studies assume that economic resources such as land, labour and capital are indefinitely available, are never idle and can be reallocated without adjustment costs. They also assume that all prices remain constant, even if demand increases. This is not realistic or credible.

The 'multiplier' type impacts were out of scope for this exercise but, if they were in scope, we would have used Computable General Equilibrium (CGE) modelling to determine for example, the economic impacts if the clinical trials sector had it not existed. CGE models are now our **preferred method for assessing economic impacts** and are used extensively in New Zealand and internationally. As a recent commentator noted regarding CGE modelling *"a well-designed model that is used by skilled practitioners to shed light on issues the model was designed to illuminate can make a significant contribution to policy debates and decision making"*.[27]

Using actual economic data, CGE models estimate how an economy reacts to major projects or changes in policy, technology or other external factors. CGE models are useful whenever we wish to estimate the effect of changes in one part of the economy upon the rest of New Zealand. CGE modelling is widely regarded as **more robust and providing more credible impact assessments** than input-output ('multiplier') methodologies.[28]

[27] Dennis, R. (2012) *The use and abuse of economic modelling in Australia,* Australia Institute Technical Brief No. 12.

[28] See Gretton, P. (2013) *On Input-output Tables: uses and abuses*. Australian Productivity Commission Staff Research Note for a thorough discussion of what multipliers are, how they are constructed and their shortcomings as tools for assessing economic impacts.

We also note that the Australian Bureau of Statistics has ceased to provide multiplier estimates from its input-output tables. https://www.abs.gov.au/ausstats/abs@.nsf/Previousproducts/5209.0.55.001Main%20Features4Final%20release%202006-%2007%20tables?opendocument&tabname=Summary&prodno=5209.0.55.001&issue=Final%20release%202006-%2007%20tables&num=&view=

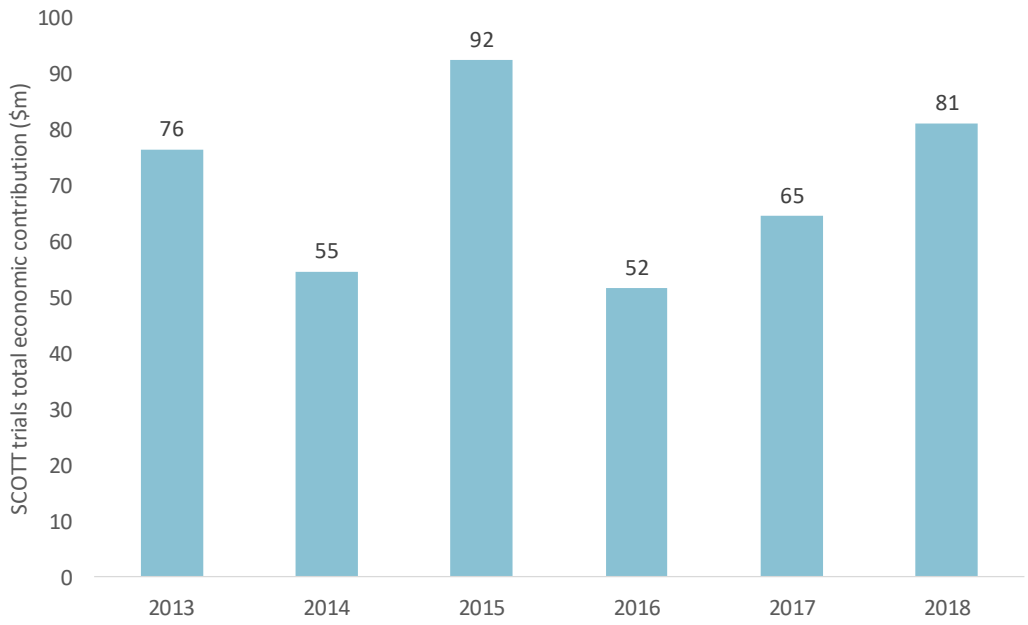
# Appendix D An alternative approach

A study of the Thailand clinical trials sector (Deloitte Access Economics 2016) determined the economic contribution of clinical trials using an alternative method. Using a combination of surveys and international comparisons, they derived a per-patient cost of conducting clinical trials in Thailand. Applying the per patient cost to the total number of patients gave the total economic contribution of the clinical trials sector.

We triangulate the per-patient costs to our SCOTT trials to determine the total economic contribution under this method. Figure 10 below shows the total contribution under this method.

### Figure 10 SCOTT trials total economic contribution using the Thailand study approach

NZ$ millions




Source: NZIER, Deloitte Access Economics 2016; Reserve Bank of New Zealand n.d.

The fluctuating pattern is consistent across this alternative approach and our approach. However, our estimates are two to three times higher and the difference in total contribution values between years are more pronounced in our approach than those predicted by the Thailand study approach. This could be due to two reasons:

1 By applying a per-patient cost to the number of patients, the study implicitly assumes that those patients were part of profit-making trials. In our dataset, there are some non-profit-making (non-commercial) trials. Since the per-patient cost cannot be applied to the non-profit-making trials, their total contribution value was changed to $0 except in instances where the funding value was publicly available, e.g. HRC grant funding. In our approach, for non-profit-making trials, we can still determine the direct

contribution value through labour income (DKM Consultants Ltd 2016; KPMG 2016; 2019).

2 The Thailand study uses economic multipliers to determine the direct and indirect contributions. NZIER does not use the economic multiplier approach for the reasons highlighted in Appendix C.

The Thailand study mentions that Phase IV trials require 40% of the resources of Phase I to III trials, which we have adopted in our approach.