# R&D Tax Incentive

## Additionality and spillovers for the life sciences industry

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December 2019

# Executive Summary

This report presents new data illustrating – for the first time – the disproportionately negative effect the proposed R&D Tax Incentive (RDTI) changes would have on the life sciences sector.

Whilst 63 per cent of respondents to the AusBiotech survey indicated that the RDTI materially influenced the decision to undertake their current level of research and development (R&D), comparative research by the Centre for International Economics (CIE, 2016) into the broader innovation sector found that only about one-third of R&D spending decisions were materially influenced by the RDTI programme.[a]

The contrast between the results in this report and the 2016 data is explained by the original survey not including specific data on the life sciences sector, whereas the new survey and case studies are solely focused on this sector.

Any proposed changes to the RDTI should be viewed in relation to how they will impact the life sciences sector; fully understood with sector-specific modelling and mitigated, before changes are enacted. If this is not possible, the safer policy path is that the broader life sciences sector should be quarantined from the proposed changes.

The RDTI is the most critical policy available to life sciences companies and so examining, analysing and understanding the additional benefits that it brings to Australia is fundamental to informed decision making.

The Senate Economics Legislation Committee found in February 2019 that the Government should reconsider its proposed reforms of the RDTI. The specific RDTI amendments in the original omnibus legislation were subsequently withdrawn but newly drafted legislation to enact changes to the RDTI is anticipated.

The available dataset in the original CIE report – on which the previous recommendations for making changes to the RDTI were based – lacked the granularity needed to capture the particular sensitivities of biotechnology research and product development.

## Key findings of the new report

- 63 per cent of respondents advise that the RDTI materially influenced the decision to undertake R&D.
- 61 per cent of respondents advise that the proposed changes would not only affect their expenditure on R&D but would also threaten the sustainability of their businesses.
- 57 per cent advise that changes would impact on the amount of R&D their companies undertake in the future.
- 29 per cent (mean) reduction in R&D was anticipated.
- Clinical trials are critically important to survey respondents, and to businesses who provide third-party services for clinical trials. However, the broader ecosystem shows that the volume of clinical trials is dependent upon the health of companies relying on broader RDTI contributions.
- As well as the additional R&D that occurs due to the RDTI, significant spillovers are also generated in relation to employment, training and skills development, together with growth of the sector and advances in health and innovation.

These data are markedly different from those captured in the CIE Report.

Whereas engineering and mining R&D have the potential to increase productivity or stimulate demand for employment, life sciences research transcends these benefits. Whereas most industries capture benefits in increased activity and income, biotechnology also offers expanded public welfare outcomes. Accordingly, additionality for the life sciences sector should include extra weighting for the health benefits (and their economic additionality) being delivered, and for activity being retained in Australia.

The life sciences sector encompasses 1,852 organisations and more than 240,000 jobs, making it a significant industry for Australia's economic growth with spillovers that offer enormous promise

a Centre for International Economics, R&D Tax Incentive Programme Review, prepared for the Department of Industry, Innovation and Science, 29 March 2016, p. 88.

for our future. R&D in the biotechnology sector is unique, both in its development challenges and in its output products. It is IP-based, heavily regulated and R&D-intensive and a highly globally-mobile industry. Life sciences offers high value jobs and a growing and sustainable contribution to GDP. Its products provide the greatest public good; from cancer treatments to helping people hear, they are life-saving and life enhancing. Biotechnology has the capacity to address the big issues of our time, such as food security, alternative fuels, ageing populations, personalised gene-based medicines and diagnostics, climate change and access to clinical trials.

The proposed changes will significantly affect many companies and have a disproportionate effect on life sciences development, especially SMEs and start-ups, which will then impact on the capacity of the sector to deliver new technologies. Patients may miss out on early access to new treatments and technologies if their country does not play a role in developing these innovations.

## Recommendation

Eight issues have been highlighted that need to be better understood before proceeding with changes to the RDTI.

These are:

1. Concerns that the calculation of additionality from a Treasury perspective does not reflect the practical decision-making processes of affected companies;
2. The incompleteness of the definition of additionality, particularly as it omits behavioural effects;
3. The treatment of companies undertaking R&D as isolated operators without taking into account the broader ecosystem and set of horizontal relationships within which these organisations coexist and collaborate;
4. The impact of reduced R&D tax benefits on the potential value of businesses and the corresponding increase in their weighted average cost of capital (WACC);
5. The implicit assumption of homogeneity across all companies undertaking R&D in Australia without identification of risks and costs particular to life sciences innovation and its spillover in clinical trials;
6. The presumption that clinical trials can be neatly (and without loss) separated from associated R&D in the life sciences. The lack of clarity around what constitutes clinical trial expenditure is an associated issue;
7. The absence of clarity around the marginal excess burden of taxation (deadweight loss) from increasing the complexity of the tax incentive; and
8. The gap between what is concluded in the CIE Report and the proposed changes to the RDTI.

Two further measures are recommended to maintain the sustainability of the high growth and job-producing potential of the Australian life sciences sector in the medium term:

- The exemption of life sciences companies from the proposed changes to the RDTI. As these represent only a fraction of the 5 per cent 'other' industries (not mining, manufacturing or Information Technology and Telecommunications) under the RDTI by value, this should not have material effect on the cost of the program; and,
- Further extensive study of the sector to better understand the extent of the sector's additionality and spillover effects.

Supporting R&D also prevents the negative effects that are the consequence of a non-competitive economy. If adequate incentives are not available to attract R&D activity, there is a risk that countries miss out on the benefits that accrue from skills transfer and skilled employment opportunities and become comparatively unattractive in the global market.

The life sciences industry drives both economic growth and patient wellbeing, raising the quality of life for all Australians.

# R&D and Innovation

In the Global Innovation Index 2019, Australia fell two rankings to place 22nd overall.[1]

In terms of innovation outputs, Australia ranked lower still. Falling one place to rank 31st in terms of innovation outputs, Australia was behind countries such as Switzerland, Netherlands, Sweden, the United Kingdom, the United States, Germany and Israel but, also, other nations including Slovenia, Estonia, Cyprus and Malta. Australia had edged ahead of New Zealand although only marginally.

## Innovation and R&D: why does this matter?

Evidence indicates that continuing investment in R&D is an important factor for many Australian businesses to maintain a global, competitive edge and remain innovative.[2] Innovative companies are more likely to increase their market share and their employment.[3] This in turn helps support national economies and GDP levels. Providing well-structured tax and other incentives and systems acts to encourage innovation within business and generate these positive spillover effects.

Supporting R&D also prevents the negative effects that are the consequence of a non-competitive economy. If adequate incentives are not available to attract R&D activity, there is a risk that countries miss out on the benefits that accrue from skills transfer and skilled employment opportunities and become comparatively unattractive in the global market. In addition, in the life sciences sector, patients may miss out on early access to new treatments and technologies if their country does not play a role in developing these innovations.

## R&D Incentives recognise the role of R&D in innovation

Numerous governments globally offer incentives to companies to undertake R&D or to boost their level of R&D. This recognises the fact that governments themselves cannot undertake or fund all R&D activity and, without financial assistance, companies will fail to undertake R&D that may deliver significant social benefit desired by governments yet not meet profit or other business targets.

The majority of countries above Australia on the Global Innovation Index, together with a large percentage of those ranked lower, offer incentives for R&D activity. These incentives take many forms, including tax credits, deductions, direct financial grants, and so forth.

In addition and in contrast to Australia, many countries have established a very stable environment and set of rules governing their system of incentives. To be competitive, Australia needs both a competitive incentive scheme and a stable one. The United States of America, for example, not only offers incentives to companies undertaking R&D activities but has essentially not changed the rules governing these since 1990.[4] This facilitates further R&D investment by enabling businesses to plan their spending on R&D activity.

1 From a total of 129 economies.
Cornell University, INSEAD, and WIPO, *The Global Innovation Index 2019: Creating Healthy Lives—The Future of Medical Innovation*, Ithaca, Fontainebleau, and Geneva, 2019. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf Accessed 28 July 2019.

2 House of Representatives Standing Committee on Science and Innovation, *Pathways to Technological Innovation*, Parliament of Australia, Canberra, 2006. http://www.aphref.aph.gov.au_house_committee_scin_pathways_report_fullreport.pdf Accessed 28 July 2019.

3 Commonwealth of Australia, Department of the Prime Minister and Cabinet, *National Innovation and Science Agenda*, 2015. https://www.industry.gov.au/sites/g/files/net3906/f/July%202018/document/pdf/national-innovation-and-science-agenda-report.pdf Accessed 29 July 2019.

4 Beth Webster and Russell Thomson, "R&D tax Incentives need to be simple and underpin investor confidence", The Conversation, 3 October 2016. https://theconversation.com/randd-tax-incentives-need-to-be-simple-and-underpin-investor-confidence-66273 Accessed 29 July 2019.

In contrast, substantive changes have occurred to Australia's R&D taxation rules every five of the last twenty years. This is despite the fact that reviews of Australia's R&D incentives report that these incentives are important influencers on the level of R&D activity for a large number of companies.[5] The House of Representatives Standing Committee on Science and Innovation, in their 2006 report, stated that "adequate and appropriate support for R&D and other innovative activities occurring in businesses is essential" and noted that business R&D activities had benefited from the support provided by the incentives offered by the Australian Government, in this case the R&D Tax Concession.[6]

This echoed the Department of Industry, Tourism and Resources' 2003 evaluation of the R&D Tax Concession which found that an appropriate and effective policy measure.[7]

The Australian National Audit Office noted however an inability of some of the measurements of R&D incentives to quantify effectively the extent to which they encouraged additional R&D investment. Numerous other reports, suggest that work needs to be done to identify the additionality generated by R&D tax incentives or the need to design R&D tax incentives such that they best encourage additional R&D spend, and also point to the inability to measure effectively the additional R&D investment undertaken because of those incentives.[8]

5 Various of the reviews into the R&D Tax Concession report this over many years, including the ANAO's Audit Report No. 40, 2002-03 into the R&D Tax Concession. https://www.anao.gov.au/work/performance-audit/rd-tax-concession Accessed 28 July 2019.
6 House of Representatives Committee on Science and Innovation, Pathways to Technological Innovation, 2006.
7 Reported in House of Representatives Committee on Science and Innovation, *Pathways to Technological Innovation,* 2006.
8 Numerous reviews into the R&D Tax Concession over many years report or highlight this issue including the House of Representatives Standing Committee on Science and Innovation's report, *Pathways to Technological Innovation,* and the Department of the Prime Minister and Cabinet's *National Innovation and Science Agenda.*

# R&D Tax Incentives in Australia

## R&D Tax Concession: development over time

The R&D Tax Concession was introduced in 1986 and, between then and its replacement with the R&D Tax Incentive in 2011, was subject to many changes.

The R&D Tax Concession was originally established as an uncapped program providing a 150 per cent tax deduction for eligible expenditure on R&D and applied retrospectively from 1 July 1985. Originally introduced as a temporary measure, in the 1992-93 Budget the then-Labor Government announced that it would be continued indefinitely.[9]

In 1996, there were a number of changes to the program. The 150 per cent deduction was lowered to 125 per cent and the eligibility criteria were tightened. In addition,the capacity for syndicates to access the concession was closed to new entrants.[10] At the same time however, and to ameliorate the impact of the changes, other measures were introduced to support R&D in Australia. These were focused providing a mixture of grants and concessional loans via the Strategic Assistance for Research and Development (START) program and business advice and assistance through the Commercialising Emerging Technologies (COMET) program.

The decrease of the Concession to 125 per cent did have consequences and was responsible, according to various commentators, for a significant downturn in business expenditure on R&D (BERD) between 1996 and 2001.

Certainly changes to the R&D Tax Concession, coupled with decreases in the corporate tax over time, saw the value of the Concession fall from 23 cents in every R&D dollar in the 1980s when the corporate tax rate was 46 per cent, to 18 cents and then to 9 cents in 2001.[11]

## R&D Tax Concession: the final iteration

Immediately prior to its replacement in July 2011, the R&D Tax Concession consisted of four key elements. These were:

- A basic 125 per cent tax concession that a company could claim on expenditure on eligible R&D via their tax return;
- A 175 per cent premium concession for certain expenditure over and above an organisation's average expenditure over the prior three years;
- A 175 per cent international premium concession where qualifying R&D expenditure was undertaken and where the associated intellectual property was held offshore; and
- A refundable R&D tax offset for small companies with a turnover of less than $5 million.[12]

9 Katrine Del Villar, "Taxation Laws Amendment (Research and Development) Bill 2001. Bills Digest no. 44, 2001-02, Parliamentary Library, Canberra, 2001. https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id:%22legislation/billsdgs/KOW46%22 Accessed 28 July 2019.

10 Del Villar, "Taxation Laws Amendment (Research and Development) Bill 2001. 2001.

11 Del Villar, "Taxation Laws Amendment (Research and Development) Bill 2001. 2001.

12 John Murray, "Tax Laws Amendment (Research and Development) Bill 2010", Bills Digest no.165 2009-10, Parliamentary Library, Canberra, 2010. https://www.aph.gov.au/binaries/library/pubs/bd/2009-10/10bd165.pdf Accessed 28 July 2019.

These provisions were outlined in Division 3A of the *Income Tax Assessment Act 1936* and were repealed by the *Tax Laws Amendment (Research and Development) Act 2011*.[13]

In the year prior to the abolition of the R&D Tax Concession, around 8,000 businesses were registered for the incentive and the investment by Government in the Concession was estimated at around $1.5 billion.

## R&D Tax Incentive

Australia's Research and Development Tax Incentive (RDTI) replaced the R&D Tax Concession on 1 July 2011 and was designed to encourage "companies to engage in R&D benefiting Australia"[14] and "stimulate productivity growth and innovation" across the wider Australian economy.[15]

This rationale for the RDTI is clearly reinforced by the Australian Tax Office which reports that it aims to "boost competitiveness and improve productivity across the Australian economy by:

- Encouraging industry to conduct R&D that may not otherwise have been conducted
- Improving the incentive for smaller companies to undertake R&D
- Providing business with more predictable, less complex support".[16]

It achieves this by providing a tax offset for eligible R&D activities and has two core elements:

- A 43.5 per cent refundable tax offset for certain eligible entities whose aggregated turnover is less than $20 million p.a.; and
- A 38.5 per cent non-refundable tax offset for all other entities. Unused offset amounts may be carried forward to future financial years.

It is worth noting that both these rates were originally higher – at 45 per cent and 40 per cent respectively. The rate of the R&D tax offset is reduced to the company tax rate for that portion of an organisation's notional R&D deductions that exceed $100 million during an income year.

Interestingly, and for the first time, the current RDTI decoupled the incentive for R&D activity from the corporate tax rate. Under the R&D Tax Concession, decreases in the corporate tax rate reduced the level of assistance offered by the Concession which was often commented on negatively during reviews.[17] The amount of support offered by the RDTI is not impacted by this.

Based on the data used in the Finkel, Ferris, and Frasier Review (see next section) in 2013-14, nearly 14,000 entities were registered for the RDTI and the benefits provided were estimated at $2.95 billion or around one third of the Australian Government support for innovation.[18]

13 Australian Tax Office, "Transition from the R&D tax concession to the R&D tax incentive", 28 February 2017. https://www.ato.gov.au/Business/Research-and-development-tax-concession/In-detail/Transition-a-R-D-tax-concession-to-incentive/ Accessed 29 July 2019.
14 Australian Tax Office, "Research and development tax incentive", 23 June 2017. https://www.ato.gov.au/Business/Research-and-development-tax-incentive/ Accessed 28 July 2019.
15 John Murray, "Tax Laws Amendment (Research and Development) Bill 2010", 2010.
16 Australian Tax Office, "Research and development tax incentive", 23 June 2017.
17 These included, for example, the House of Representatives Standing Committee on Science and Innovation, *Pathways to Technological Innovation,* 2006 and the Senate Finance and Public Administration Committee, *Inquiry into Business Taxation Reform*, Parliament of Australia, Canberra, 1999. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Finance_and_Public_Administration/Completed_inquiries/1999-02/btr/report/contents Both accessed 28 July 2019.
18 Bill Ferris et al., "Review of the R&D Tax Incentive", Department of Industry, Innovation and Science, April 2016. https://www.industry.gov.au/sites/g/files/net3906/f/May%202018/document/pdf/research-and-development-tax-incentive-review-report.pdf Accessed 20 July 2019.

## Proposed changes to the RDTI

A review into the RDTI reported to the Prime Minister in April 2016. This Review was initiated as part of the National Innovation and Science Agenda and undertaken by Bill Ferris AC, Chair Innovation Australia; Dr Alan Finkel AO, Chief Scientist; and John Fraser, then Secretary to the Treasury. The Review made key recommendations to change the RDTI, although the policy changes that the Government actually proposes were not revealed until Budget night 2018.

The details of the proposed measures are complex but largely focus around a number of key changes that impact the life sciences sector. These are:

- Fixing the rate of the refundable R&D Tax offset to 13.5 per cent above an organisation's tax rate for companies with a turnover under $20 million;
- A $4 million cap on cash refunds, with an exemption from this cap for clinical trial work;[19]
- An R&D Premium for conducting 'high intensity' R&D for companies with an annual turnover of over $20 million; and
- An increase in the R&D expenditure threshold rate from $100 million to $150 million.

An Inquiry conducted by the Senate Economics Legislation Committee found in February 2019 that the Federal Government should reconsider its proposed reforms of the RDTI. The specific RDTI amendments in the original omnibus legislation were subsequently withdrawn. Newly drafted legislation has now entered the paliament with key features of the previous Bill.

### *Fixing the rate of the refundable R&D tax offset*

The proposal to fix the refundable R&D tax offset to 13.5 per cent above an organisation's tax rate means an effective reduction in this rate from 43.5 per cent to 41 per cent - a proposed change that would see life sciences companies with turnover of less than $20 million lose a portion of their cash refund that they can ill-afford to forego.

This change will be both significant and material for many life sciences companies as, for each $1 million of expenditure, they stand to lose $25,000. Furthermore, this would have a disproportionate effect on smaller organisations including SMEs, start-ups and the like. These make up a large proportion of Australia's life sciences sector and, as a result, these changes would impact on the capacity of life science organisations to develop and bring to market the products with which they are involved and which have the potential to positively impact the health and wellbeing of Australians.

Furthermore, this reverses the position taken in the construction of the original RDTI and recouples the tax offset available to companies to the company tax rate. Given past experience, it is also likely that the value of the benefits being delivered to companies will vary over time.

### *A $4 million cap on cash refunds, with an exemption for clinical trial work*

It is also proposed to introduce a $4 million cap on the annual cash refund that can be paid under the RDTI with any remaining offsets to be treated as a non-refundable tax offset that can be carried forward into future years.

Whilst the exemption of clinical trials from the $4 million cap has been largely welcomed by the life sciences sector, this welcome has been tempered by the high degree of confusion that remains about which expenditure would be eligible for the RDTI under the proposed changes.

19 The precise scope of this exemption is unclear. This is discussed further below.

### *An R&D premium for conducting 'high intensity' R&D*

An R&D Premium is proposed for companies with aggregated annual turnover of $20 million or more. This will link the rate of the non-refundable R&D tax offset that a company will receive to the incremental intensity of their R&D expenditure as a proportion of their total expenditure. The marginal R&D Premium for a company would then be the organisation's company tax rate plus:

- 4.5 per cent for R&D expenditure between 0-4 per cent R&D intensity;
- 8.5 per cent for R&D expenditure for R&D intensity of 4-9 per cent; and
- 12.5 per cent for R&D expenditure over 9 per cent R&D intensity.

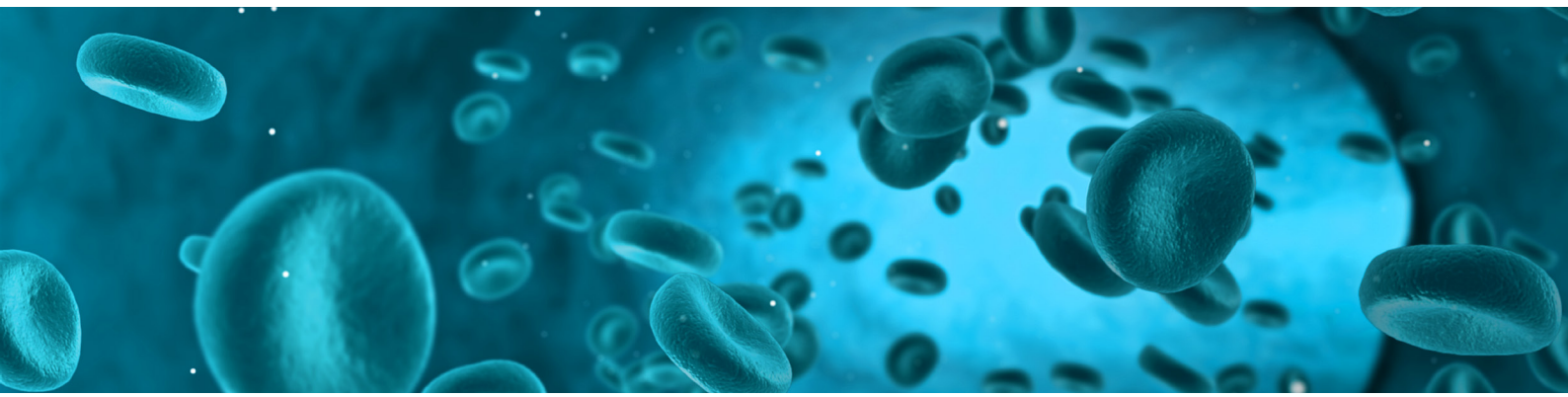
Most larger companies in the life sciences sector anticipate that the introduction of this measure will see a reduction in support for most of them, coupled with significant complexity and uncertainty about eligibility. Given that Treasury estimates that 180 claimants of the non-refundable R&D tax offset will receive a higher offset under the proposed changes and 14,000 companies are registered for the RDTI at present, 98.8 per cent of companies can be expected to be worse off under the proposed changes.[21]

The measure, if enacted, will prove hard to estimate in advance which undermines the certainty that most companies have traditionally had in relation to future RDTI calculations. This in turn will then undermine companies' ability to plan. The calculation further disadvantages companies with high capital expenditure, such as manufacturers.

### *An increase in the R&D expenditure threshold rate from $100 million to $150 million*

The proposed changes also include an increase in the R&D expenditure threshold rate from $100 to $150 million. The rationale behind this is to maintain an incentive for companies with large R&D expenditure to increase their Australian R&D. While this is welcome, it is only applicable to a few companies, with the potential addition of one or two more in years to come. As such, it should not be seen as a commensurate exchange that justifies the changes.

21 https://parlinfo.aph.gov.au/parlInfo/download/committees/commsen/147d8aa4-1a92-47f4-8e58-0d5d6f02b132/toc_pdf/Economics%20Legislation%20Committee_2018_11_16_6771_Official.pdf;fileType=application%2Fpdf#search=%22committees/commsen/147d8aa4-1a92-47f4-8e58-0d5d6f02b132/0000%22



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## Case Study One: Impact of Uncertain Policy Environment on Business

Company X is a biotechnology company listed on the Australian Securities Exchange, and originally operated to commercialise biomedical research before deciding to focus on developing biologically based therapies. It therefore has traditionally operated a number of research projects and has been responsible for spinning out a number of Australian biotechnology companies in the decades since its formation.

More recently however, the company has focused on the opportunities in a particular disease area and currently has large international clinical trials underway in both phases 2a and 2b. This has followed a long period of pre-clinical development followed by phase 1 trials.

The company has claimed the RDTI for a number of years. The development of their research program has seen this claim grow substantially over the last few years, from around $2 million to nearly $15 million.

The company is clear that the RDTI can set companies apart when they are seeking investment capital and that overseas investors see the RDTI as a cost-effective means of maximising their investment.

At the same time, the uncertainties in relation to the RDTI and the proposed changes to it have created significant internal challenges. For a period of over six months, it is estimated that around 75 per cent of each board meeting was dedicated to planning for the impact of the potential changes.

In addition to the significant time dedicated to risk mitigation, substantial resources were expended analysing and modelling the potential impacts. Board papers were prepared in advance of every board meeting that modelled scenarios including carve outs of clinical trials, the impact of caps and potential changes in the rates applicable for the RDTI.

Uncertainties therefore arose about the capacity of the organisation to fund its projects to completion. Consideration had to be given to how additional capital might be raised and it became essentially 'impossible to plan' in an environment of deep policy uncertainty.

Further, the uncertainty about the future of the RDTI resulted in the company failing to maximise their capital. Instead of spending capital as planned and generating the resultant jobs and investment, expenditure was delayed. Investors had to be updated about the situation given that it was material to the company and this potentially also impacted on other investments they may have contemplated during the period.

This impact should not be underestimated. When considering the people, jobs and activities impacted by the company and potentially by the uncertainty of the environment, and the requirements of full market disclosure, the complexity of the ecosystem for life sciences is brought into stark relief. This organisation notes its involvement and reliance on numerous groups outside their direct employment in order to deliver on their project. These include:

- Regulatory experts who establish and monitor systems for clinical trials, write Standard Operating Procedures and ensure that the company maintains appropriate filing and other systems for the collection of data to ensure regulatory records;
- Advisors across areas as diverse as audit, tax and legal expertise;
- Contract research organisations, including Australian-based organisations;
- Manufacturing facilities that manufacture product for use in clinical trials;
- The distributors of these products; and
- CSIRO, with whom the organisation has had more than 50 projects in basic research during its existence.

Whilst noting that these groups are not direct employees of the company, they are integral to its progress and success and an essential part of the ecosystem that enables its ongoing research and commercialisation activities.

# The Life Sciences Ecosystem

With more than 1,852 organisations and 240,000 employees, Australia has a substantial life sciences sector and one which is consistently ranked as one of the top for biotechnology innovation.[22] The life sciences offer the opportunity to underpin Australia's future economy as well as provide solutions to a wide range of challenges.

The broader life sciences sector undertakes a number of different activities. It can involve food technology, agritech, digital health and biotherapeutics as well as the more 'traditional' activities of therapeutic and pharmaceutical development.

For the purposes of this report, however, life sciences refers to those organisations involved in and committed to health and medical research only. As such, the "life sciences sector" refers to the diverse organisations, which range from universities to start-up and spin-out companies, contract research organisations, both public and private, clinical trials units and research, as well as biotechnology and large pharmaceutical companies, that are engaged in health and medical research. These organisations may be publicly listed or not, operate domestically and/or internationally, and have a small or large number of employees.

What is critical about these companies is their interrelationships. No single part of the life sciences sector can thrive without the others. The time and investment (see next section) required to develop, for example, a new medicine is such that no single entity identifies the successful molecule and then develops it through the clinical trial process to commercialisation any longer. Whilst this was once the case, the sector has become increasingly inter-dependent such that numerous organisations will now all work on a product to achieve this outcome. This means that the sector has become increasingly reliant on its own ecosystem and the success of one part of that ecosystem now requires the success of other parts of the system also.

This is certainly the case in Australia where both the opportunity and the ambition for life sciences research are significant. Looking at an example, the emerging field of regenerative medicine is poignant. There is an expectation of a global market in 15 years of some A$120 billion. Capturing 5 per cent of this would bring Australia an incremental 6,000 jobs and A$6 billion in revenue by that point.[23]

Given the opportunities in life sciences going forward, protecting the ecosystem surrounding the sector becomes ever more important, particularly where a government or a country is keen to develop the jobs of the future and future success in this area.

This type of ambition is reflected in Australian Government policy. In particular, the $20 billion Medical Research Future Fund notes as its first priority to:

> *Support stronger partnerships between researchers, healthcare professionals, governments and the community. This will help position Australia as a leader in significant global research, such as tackling antimicrobial resistance.*[24]

22 AusBiotech, *Biotechnology Industry Position Survey,* 2019.
23 AusBiotech, *Biotechnology Industry Position Survey*, 2019.
24 https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund/about-the-mrff/mrff-strategy-and-priorities Downloaded August 2019.

## Time and costs in developing successful life sciences products

The time and costs to develop successful products in the life sciences sector is radically longer than that in most industries. The Tufts Center for the Study of Drug Development found that the current cost of developing new prescription medicines to the point of marketing approval is estimated at US$2.6 billion.

This compares to the same study in 2003 which found that the cost was $802 million. Adjusted for inflation, this represents a 145 per cent increase over 10 years.[25]

The $2.6 billion cost of development captures both $1.4 billion of direct out-of-pocket costs and also $1.2 billion of expected returns that investors forego whilst a medicine is being developed.

The reasons for these costs relate in part to the long timeframe needed for medicine or biological product development. The R&D process has significant technical risks and multiple stages through which a product must pass from pre-clinical laboratory research through to phase 1 or first-in-human trials and then phase 2 and 3 clinical trials. Regulatory assessment is required throughout clinical development before products then progress to formal consideration by organisations such as Australia's Therapeutic Goods Administration before being made available to the public.

The timeframes involved in this development process are significant taking from 12 to nearly 15 years.[26]

Critically, companies are often not generating revenue during this period. These timelines, costs incurred and absence of revenue (or minimal revenue) is why this period is described as a 'valley of death' for life sciences companies.

This is not to suggest that life sciences are purely about the development of medicines but is designed to provide an indication of the timeframes and scale of investment needed in this sector. With timeframes reaching over a decade and investment of this scale, it is clear that the life sciences sector faces a myriad of challenges different from those of other industry sectors.

## Partnerships and collaboration

The issue of partnerships and collaboration in biotechnology is fundamental. As a great deal of early stage research takes place on university campuses via matched and grant funding, academic-industry partnerships are a common starting point. These partnerships are the transition point from science to potentially commercial technology.

Many of these relationships are funded by cooperative grants, Cooperative Research Centres and the like, and many are funded directly by companies including SMEs. Evidence shows that the productivity of such arrangements grows with the number of partners.[27] One of the drivers for such collaboration is the continuing reduction in internal R&D success within pharmaceutical and other biotechnology companies.[28]

25 Thomas Sullivan, "A Tough Road: Cost to Develop One New Drug is $2.6 billion; approval rate for drugs entering clinical development is less than 12%", *Policy and Medicine*, 21 March 2019. https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html Accessed 10 August 2019.

26 International Federation of Pharmaceutical Manufacturers & Associations, *Incremental Innovation: Adapting to Patient Needs*, 2013. https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf Accessed 15 August 2019.

27 Sen Chai and Willy Shih, "Bridging science and technology through academic-industry partnerships", *Research Policy*, No.45, 2016, p.156.

28 Dominique Kleyn & Richard Kitney, "Partnership and Innovation in the Life Sciences", *International Journal of Innovation Management*, Vol.11:2, June 2007, p.341.

The importance of clusters of ideas and money in life sciences emphasises the need for a working ecosystem with the opportunity to find reliable and appropriate partners. A study of biotechnology research around San Diego, around the University of California campus and close to Californian venture capital (VC) clusters, show a range of features of a successful ecosystem. These include:[29]

- Critical mass, which permits expansion and diversity, providing good partnership prospects;
- Leadership capability, to provide the management which is not often characteristic of the scientific research community;
- Renewal, as companies succeed to IPO, and become investors in the next cycle; and,
- Convergence, in this case between clusters of life sciences and wireless technology.

The success of the United States in this space is not simply due to scale, money or cultural factors but also is a clustering effect. Compared to the partnership innovation success of the United Kingdom, the United States is far ahead because it fosters hubs with high diversity of innovative labour.[30] Other studies emphasise this issue of diversity in decentralised networks, noting in relation to growth the natural development of:[31]

> *… a network structure in which multiconnectivity expands as the cast of participants increases, and, in turn, diversity becomes more important with time.*

This follows the broader trend toward *economies of agglomeration*, where higher wages and other productivity benefits are a characteristic of more dense economic zones.[32]

Tax incentives are a critical tool for assisting countries like Australia to develop their life sciences sector and allow it to catch up, however incrementally, with the United States' more mature life sciences sector.[33] There is strong argument that government support is more important in countries who have been later participants in life sciences and have limited VC markets, like Australia, and high ratios of startups. Additionality is higher for government support in these markets.[34]

There are other activities which will assist at the post-campus stage, such as open innovation. This is the provision of hubs with shared resources, including capital and expertise, to stimulate knowledge exchange and defray innovation cost.[35] But the clusters still need to be natural aggregations as the history of artificial hubs is not positive.

Why this all matters in terms of the proposed revisions to the RDTI is twofold. First, these clustered networks are fragile. Scale is important for natural diversity, whether in ideas, collaborators, financiers and late-stage developers or buyers. If any of these groups has a reduced incentive to participate in the Australian market, there is a risk of a reduction in a key component of the ecosystem. This is likely to be a cascading effect in which the departure of one participant for greener tax pastures leads partners to the same jurisdiction, causing a chain reaction of departure and a reduction in confidence in the market.

29 Jukka Majava, Satu Rinkinen and Vesa Harmaakorpi, *Development of San Diego Life Sciences Ecosystem*, 2017: http://tem.fi/documents/1410877/4430406/Jukka_Majava_Satu_Rinkinen_Vesa_Harmaakorpi.pdf/f9e58545-7129-4adb-8fd8-b61ec02b946a Downloaded July 2019.

30 Jason Owen-Smith et al, "A Comparison of U.S. and European University-Industry Relations in the Life Sciences", *Management Science*, Vol. 48:1, 2002, pp.40-41.

31 WW Powell et al, "Network dynamics and field evolution: The growth of interorganizational collaboration in the life sciences", *American Journal of Sociology*, 110:4, 2005.

32 See Edward L Glazer, *Agglomeration Economics (National Bureau of Economic Research Conference Report)*, University of Chicago Press, 2010.

33 i.e., successful clusters act as attractors, even internationally, and limit growth in secondary market clusters.

34 Kwangsoo Shin et al, "Government R&D Subsidy and Additionality of Biotechnology Firms: The Case of the South Korean Biotechnology Industry", *Sustainability*, 11, 2019.

35 For an illustration of the model, which is particularly prevalent in Northern Europe, see: Robert Kirschbaum, "Open Innovation in Practice", *Research Technology Management*, July 2005.

Second, networks are not well-supported by preferring one participant to another in the tax regime. Imagine a collaboration between a US multinational and an Australian startup. According to the proposed changes in 2018, the startup needs tax relief more than its partner. But, if the partner loses the incentive to be in Australia, then it will either vacate or export the entire partnership, either taking Australian innovation prematurely overseas or leaving the startup an orphan. Orphan R&D firms are not attractive for capital raising.

There is a tendency in the Regulatory Impact Statement (RIS) and the Review to see claimants of the RDTI as having a principally vertical relationship with the Tax Office. From this perspective, structuring tax according to scale and intensity makes sense.

> ***The RDTI is more important in supporting the broader ecosystem within which life sciences seek to flourish and this is not well-served by preferring one group over another.***

However, from an economic perspective, the RDTI is more important in supporting the broader ecosystem within which life sciences seek to flourish and this is not well-served by preferring one group over another. It is also important to be cautious about the over-interpretation of data. Recent AusBiotech data shows a number of companies with substantial scale relative to their numbers of direct employees. What this suggests is that much of the employment is generated in extended networks, dependent upon a central recipient of project finance. This is also demonstrated in Case Study One.

This is a distinct feature of biotechnology, though it may find resemblance in other fields which has their roots in pure research rather than applied R&D.

> ***Why this all matters in terms of the proposed revisions to the RDTI is twofold. First, these [life science] clustered networks are fragile... Second, networks are not well-supported by preferring one participant to another in the tax regime.***

2

## Case Study Two: Contribution to the Ecosystem

Life sciences companies in receipt of the RDTI are deeply cognisant of the benefits it generates.

Consultations for this report saw numerous organisations describe the RDTI as 'critical', 'essential' and a 'good door-opener' with overseas companies and investors. These companies equally saw the ecosystem in which they operate as a key element of their success and they are committed to building and contributing to it.

One CRO indicated that changes to the RDTI would impact around 70 per cent of their clients and would most likely result in their own closure. This firm and others spoke of the investment and time they spend within their network to encourage and support the development of skills, talent and awareness of the Australian life sciences sector.

Much of this contribution relates to universities, with one company reporting that they host 12 or more graduates annually and have board members who sit on various university advisory councils. This company is involved in shaping university curriculum so that graduates are job-ready and are also working to develop a new higher education degree course to ensure 'real' and needed skills are taught. They also sponsor multiple Ph.D. students who, as part of their Ph.D., are funded to travel overseas, again building their knowledge and real work experience.

These 'town and gown' relationships underpin a fragile sector, each node of which is dependent upon various others, and each of which is either directly or indirectly vulnerable to changes to the RDTI.

Further, the company regularly hosts visitors and other groups, such as trade delegations, to their facility, working with their State Government to highlight opportunities available for working and investing in Australia. Company representatives also participate in overseas trade promotion as part of inward investment attraction.

This has both flow-on benefits to the company itself but also to the sector and the broader economy. Flying staff and potential investors costs the company more than $1 million a year in international flights and bringing people to Australia offers opportunities to local car companies and tourist facilities as the company highlights Australia together with the R&D environment on offer here.

This company is not alone in its approach to the life sciences ecosystem or to its investment in it with other companies highlighting collaborations and working relationships with hospitals, academics and ancillary providers of services and goods.

Over time, this investment has paid off for the nation with various consultations also stressing the change of international attitudes and approaches to Australia over the last 10 to 15 years. Whilst numerous consultations commented about recognition and investment from the United States, a clear trend was the growing recognition of Australia from China and Korea. Given that these countries' domestic investment is also growing, being able to attract these funds is critical and the quality and support of the life sciences ecosystem is vital to maintaining and growing this source.

> ***"One CRO indicated that changes to the RDTI would impact around 70 per cent of their clients and would most likely result in their own closure."***

3

## Case Study Three: RDTI's Role in Developing Researchers, Scientists and Entrepreneurs

Companies in receipt of the RDTI have a critical role in developing Australia's future life sciences employees and entrepreneurs.

During consultations for this report, it became clear of the role that a successful biotech, start up or spin out has in generating the knowledge and enthusiasm for people to explore projects in life sciences and 'snowballing' people through organisations.

An example was provided about Biota, the first Australian biotechnology company to take a product through to market.

Biota was established in 1985 and, in 1990, signed an agreement with the Glaxo Group to fund research and development of influenza products. Biota was listed on the Australian Securities Exchange in 1992 and the Biota Chemistry Laboratory established at Monash University in 1995. The company subsequently moved to purpose-built laboratory and office facilities in Notting Hill from 2005 and employed up to 100 staff.

In 1998-99, the company released Relenza, for the treatment of influenza, and a diagnostic product also for influenza.[36] Biota's R&D team and capability grew substantially for more than a decade from 2000. Research from Biota's scientists led to collaboration and licensing agreements with MedImmune and AstraZeneca (for Respiratory Syncytial Virus (RSV) antivirals), Boehringer Ingelheim (Hepatitis C drugs) and Daiichi-Sankyo (long acting neuraminidase inhibitors for influenza). Funding for multiple programs was also received from the US NIH, AusIndustry and the Wellcome Trust.

During this time, drug candidates were advanced into successful clinical trials including drugs for RSV, human rhinovirus and influenza. Throughout this period Biota's R&D growth and success was underpinned by the predecessor to the RDTI, the R&D Tax Concession.

Biota delisted from the ASX in November 2012 and closed its Melbourne operations in June 2015. This saw at least 55 researchers and scientists made redundant and was ultimately due to the collapse of a substantial funding deal from the Biomedical Advanced Research & Development Authority (BARDA, US) for development of Inavir®, a long acting drug under development to prevent and treat influenza.[37]

Since then, these researchers, scientists project managers and other specialists have moved onto other roles, many in the Australian life sciences sector. Their skills, knowledge, and expertise and experience at Biota led many to developing new companies, exploring innovative products and research pathways and supporting the sector in a variety of roles as a result of their commercially focussed R&D experience following the closure of Biota in 2014/15.

Specialist laboratory services company, 360biolabs, for example, was co-founded by R&D leaders from Biota in 2015 as a joint venture with the Burnet Institute. The current Executive are all ex-Biota staff and have built the company to 26 employees, 10 of whom were previously employed at Biota as research scientists, project managers and information specialists.

One of the co-founders of 360biolabs has subsequently moved to become CEO of two other related biotech companies.

Overall, the researchers from Biota have currently gone on to work in nine other life science

36 Biota Holdings Pty Ltd, https://www.intelligentinvestor.com.au/company/Biota-Holdings-Limited-BTA-249215 Accessed 16 August 2019.

37 Mitchell Bingemann, "Scientists sacked as Biota departs", *The Australian*, 4 June 2014. https://www.theaustralian.com.au/business/companies/scientists-sacked-as-biota-departs/news-story/75581d0a5cb5394f7c004f3f2813811f Accessed 16 August 2019.

companies; two universities or research institutes; and two government departments. The life science companies include newer, smaller organisations, large multinational pharmaceutical companies and domestic start-ups. Scientists and chemists from Biota now ply their skills at IP Australia and the Therapeutic Goods Administration as patent examiners and evaluators respectively whilst others have gone on to work as application specialists, program managers; principal research scientists; process research chemists; and bioinformatics analysts.

This is not a unique story and represents only the contributions that the research team at Biota have made in Australian life sciences since the company ceased operations in Australia. Taking skills learnt in one organisation, these individuals have transferred them to help grow the innovative industry thereby creating the'snowball' effect necessary to build a mature sector.

This research team is only one part of the equation though, with a similar story that could also be told about the development team at Biota and their onward progress. These scientists, researchers and developers represent part of the critical mass needed for the Australian life sciences sector to continue to develop, innovate and grow, underpinned by the RDTI.

## Critical elements specific to the life sciences ecosystem

- With more than 1,852 organisations and 240,000 employees, Australia has a substantial life sciences sector and one which is consistently ranked as one of the top for biotechnology innovation.
- This paper specifically uses life sciences sector to refer to those organisations involved in and committed to health and medical research only. This may include universities, start-up and spin-out companies, contract research organisations, both public and private clinical trials units and research as well as biotechnology and large pharmaceutical companies.
- In life sciences, interrelationships are critical - no single part of the life sciences sector can thrive without the others.
- Given the opportunities in life sciences going forward, protecting the ecosystem surrounding the sector becomes ever more important, particularly in relation to developing the jobs of the future.
- The time and costs to develop successful products in the life sciences sector is radically different from that in most industries, often involving billions of dollars and development periods of between 12 and 15 years.
- The skills, knowledge and expertise developed by researchers and others in the life sciences sector enables them to leverage these capabilities to generate new companies, explore innovative products and research pathways and supporting the sector in roles across universities and research institutes, government departments and other life sciences companies, including small start-ups through to large multinational pharmaceutical firms.

# Economic Commentary: Introduction

This section of the report tests the methodology and conclusions which underpin the proposed changes to the RDTI.

In particular, the focus is on the treatment of additionality and spillover effects, and consequent recommendations for tax reform, contained in:

- The Centre for International Economics' (CIE) Final Report of the R&D Tax Incentive Programme Review;[38] and,
- The Department of Prime Minister and Cabinet's Regulation impact statement: Better targeting the Research and Development Tax Incentive (the RIS).[39]

From the outset, it is important to clarify that this report is not a criticism of the CIE report, which is rigorous in its methodology, while at the same time acknowledging the limitations of available data.

The principal conclusion is not that there is any inherent deficiency in either of these documents (although the RIS is unusually thin in its analysis), but rather that they consider a market for research and development which fails to consider the particular characteristics of the life sciences sector.

Concerns under this heading fall broadly into eight categories:

1. Issues with the model for calculation of basic additionality;
2. The incompleteness of the definition of additionality, particularly as it omits behavioural effects. There is some overlap here between additionality and spillovers;
3. The treatment of businesses undertaking research and development (R&D) as isolated operators, without taking into account the broader ecosystem and set of horizontal relationships within which these companies coexist and collaborate;
4. The impact of reduced R&D tax benefits on the potential value of businesses and the corresponding increase in their weighted average cost of capital (WACC);
5. The implicit assumption of homogeneity across all businesses undertaking R&D in Australia without identification of risks and costs peculiar to life sciences innovation;
6. The presumption that clinical trials can be neatly (and without loss) separated from associated R&D in the life sciences. The lack of clarity around what constitutes a clinical trial is an associated issue;
7. The absence of clarity around the marginal excess burden of taxation (deadweight loss) from increasing the complexity of the tax incentive; and,
8. The gap between what is concluded in the CIE Report and the proposed changes to the RDTI.

With respect to the final point, there is broad concern that the conflation of changes to the RDTI with the broader issue of appropriate taxation of multinationals is a source of overreach. Having said that, it is worth acknowledging both:

- The very reasonable desire to ensure

38 Centre for International Economics, *R&D Tax Incentive Programme Review*, prepared for the Department of Industry, Innovation and Science, 29 March 2016.

39 Australian Government Department of Prime Minister and Cabinet, *Regulation impact statement: Better targeting the Research and Development Tax Incentive*: http://ris.pmc.gov.au/sites/default/files/posts/2018/11/better_targeting_the_research_and_development_tax_incentive_ris.pdf Downloaded July 2019.

multinationals are not excessively using the Australian Treasury as part of their tax planning and allocating more than the true domestic share of R&D while hypothecating income to overseas markets with lower company tax rates; and,

- The pursuit of allocative efficiency, to maximise the economic benefits from any tax incentives and ensure investment in R&D is productive.

However, the case for the proposed changes are at best incomplete, particularly as it relates to the life sciences sector. Accordingly, more investigation is required before changes to the rules affecting this industry.

For the moment, this report predominantly covers structural and environmental concerns about the treatment of the life sciences sector, to identify limitations of applying the overall model and proposed legislative reform as they stand.

Unfortunately, advice from Government is that the original data set on which the CIE report is based is no longer available. With the assistance of AusBiotech, comparative data has been gathered from a number of life sciences companies and a number of conclusions are drawn in following sections.

In the meantime, any proposed changes to the RDTI should be delayed to enable longer survey time and more extensive consultation in order to permit sector-specific modelling. If this is not possible, then the safer policy path is that the broader life sciences sector should be quarantined from the proposed changes.

Any quarantine or exceptions for the life sciences section will require a clear definition of what is contained in “life sciences”. This is also true of the need to further clarify the definition of clinical trials in the context of its exemption from the proposed changes.

It is also worth noting that the proposed changes to the RDTI as prepared in 2018 includes some backdating of changes. Given the long development cycle typical for life sciences research, which usually includes commitments of at least five years, any future changes should at least grandfather current investments. This will assist with current commitments though it will not ameliorate the broader risks to the sector, an issue that has been raised in a number of consultations.

# Calculating (Financial) Additionality

The CIE in their report use a sophisticated blend of proprietary additionality calculation – originally developed in 2003 – to estimate financial additionality with multiple parameters. This permits consideration of structural issues and input constraints, which affect capacity for additionality and thereby limit the efficiency of any targeted incentive.[40]

As noted above, the data used for these calculations are no longer available and it is unclear how many in the life sciences sector participated in the original consultation process. The CIE note as one limitation that much of the consultation underpinning their report was with tax managers in R&D companies, rather than those people making decisions about the investment in R&D.[41]

At its most direct, the CIE defines additionality via the following formula: $\sum_{i \in K,L,M,T,C,O} \sum_{j \in K,L,M,T,C,O} \varepsilon_{ij} s_i$

Where:

- $K, L, M, T, C, O$ are different inputs consumed by the company undertaking the R&D
- $\varepsilon_{ij}$ is the elasticity of demand for R&D component $i$ with respect to the change in the price of the component $j$
- $s_i$ is the share of component $i$ in overall R&D expenditure.[42]

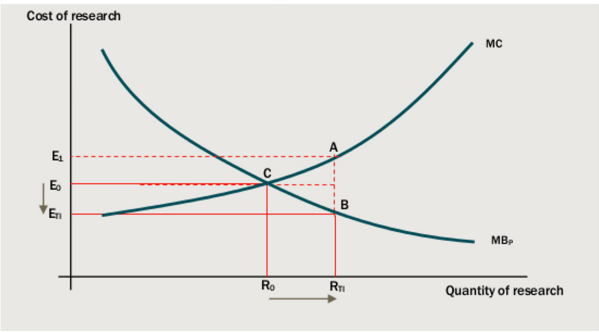
At root, what this captures is the capacity to purchase more of the input components of R&D, including labour, plant and consumables, costs of collaboration and intellectual property amongst others, when there is an effective price subsidy via the RDTI.

This is a strong basic model. It recognises that the difference between one firm and another in responding to any financial incentive (whether a grant or a tax concession) is conditioned by its idiosyncratic elasticity of demand.

Drawing upon this, it is worth noting the implicit assumption in the earlier Bill that there must be greater elasticity of demand amongst small companies than for large businesses. This is not an entirely reliable assumption as evidence from Canada, where tax credits are substantially higher, shows only slightly higher elasticity figures than for larger enterprises: with a CAD return of 2.98:1 for small companies and 2.79:1 for large businesses.[43] This is a measure of additionality which reflects relatively close observed elasticities. Other studies report elasticities at similar rates.[44]

Another expression of the valuation of additionality is given by Figure 1.

**Figure 1: Additionality Ratio**[45]




40 CIE Report, p.200-208.
41 CIE Report, p.61.
42 CIE Report, p.200.
43 Rufin Baghana and Pierre Mohnen, "Effectiveness of R&D tax incentives in small and large enterprises in Québec", *Small Business Economics*, Vol. 33, 2000, p.102.
44 See for example: Antoine Dechezleprêtre et al, *Do Tax Incentives for Researc Increase Firm Innovation?* An RD Design for R&D, National Bureau of Economic Research Working Paper No.22405, July 2016.
45 CIE Report, p.29.

Where: $\frac{R_0 CAR_{TI}}{E_1 ABE_{TI}}$

**MC** is the marginal cost of R&D

**MBp** is the (private) marginal benefit to the firm of R&D

**TI** is the Tax Incentive

The amount of additionality is given by:

The principle here is twofold:

- In practice, **TI** permits consumption of R&D inputs at a higher gross marginal cost, so leads to greater activity; and,
- The growth in **MBp** is paralleled by a simultaneous growth in community benefits **MBc**[46] which is the argument for public investment in what would otherwise be apparently private research activity.[47]

On the latter point, it is the addition of publicly-consumed benefits that supports a greater optimal level of R&D than would naturally occur in the profit-maximising organisation.

The only concern here is the calculation $\frac{R_0 CAR_{TI}}{E_1 ABE_{TI}}$ as a representation of additionality. From a practical perspective, it is hard to view the area $E_1 ABE_{TI}$ as a representation of the impact of the tax incentive as it is experienced by a company undertaking R&D.

In practice, if additionality represents the quantity of research which would not be undertaken *but for* the tax concession, then it might be better to simply consider the increase in that quantity in the presence of the concession.

In this case, a primary measure of additionality (from which an elasticity figure might be derived) could be given by the ratio:[48]

$$Additionality = \left[\frac{OE_1 AR_{TI} - OE_o CR_o}{OE_o CR_o}\right] / R_{TI}$$

Where $R_{TI}$ is the rate of the RDTI either as experienced by the company undertaking the R&D or expressed as the rate of charge on the Treasury. This gives the basis for an alternative benefit-cost analysis.

This is consistent with other Australian approaches, one of which summarises additionality with respect to the RDTI as:[49]

$$Additionality = \frac{R\&D_{1/1} - R\&D_{1/0}}{T_{1/0} - T_{1/1}}$$

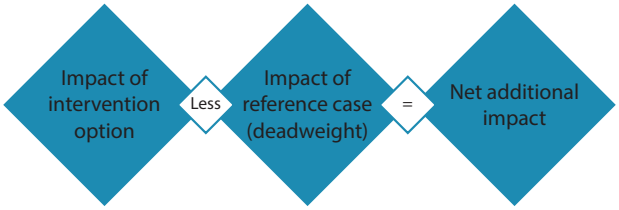
This is self-explanatory, providing a simple ratio between the increase in R&D from one period to the next and the income foregone by the Treasury over the same period. It provides a direct benefit-cost comparison, whereas this report's proposal is to compare the ratio to the rate.

A key issue for assessment of R&D tax rules is that, for many biotechnology companies, in practice there is only (from the above equation) the area $OE_1 AR_{TI}$. This is simply because, in the absence of a tax incentive, no research would be undertaken by these companies. In this case, the additionality is a substantial multiple of the tax incentive. This would be consistent with the United Kingdom's HMRC study, which focused on the short-term elasticity of tax incentives in that nation, although it is described in the report as an outlier.[50]

This is important, when we think of simple additionality (the numerator of all additionality equations) as demonstrated in Figure 2.[51]

46 This is a parallel downward-sloping curve to the right of MBp.
47 There are also other benefits such as economic robustness to address structural adjustment.
48 Here $0$ is simply the origin.
49 Russell Thomson and Ahmed Skali, *The Additionality of R&D Tax Policy in Australia*. Swinburne University of Technology Centre for Transformative Innovation, February 2016, p.7.
50 CIE Report, p.55.
51 UK Government: English Partnerships, *Additionality Guide: Method Statement, Third Edition*, p3: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/191511/Additionality_Guide_0.pdf Downloaded July 2019.

**Figure 2: Net Additionality**




The deadweight here is the amount of activity undertaken without the RDTI. For large companies, this is inevitably a positive number. But for smaller businesses, particularly those in life sciences facing unique challenges (see pages 13-14), the incentive itself may be the entire 'but for' test. It is in this sense a kind of tipping-point, which provides a stop/go for research or commercialisation.

There is an associated issue here which is that, in calculating total additionality, there is little insight available into what is happening at the margin. It is axiomatic that R&D does not operate like a commodity, but is a lumpy activity which requires addition of new programs, not simply marginal increase in expenditure. So a small change in tax efficiency for even a large company may make the difference between approving or declining a major new investment.

The counter-hypothesis here would be that organisations direct capital previously allocated to R&D elsewhere and use the tax benefit to subsidise projects which would still occur otherwise. This would be a crowding-out effect, as opposed to the intended crowding-in of the RDTI. While there is argument for this phenomenon in foreign jurisdictions with very high public support levels,[52] it is not a feature of life sciences R&D in Australia, due to:

- The large number of SME companies who report the importance of the RDTI to incremental research; and
- The mobility of research funding for multinationals, which makes the incentive important to locating activity in Australia.

Displacement of private funding by public sources appears to be more likely where there is a non-random selection or self-selection of funding targets:[53] i.e., with subsidies rather than tax support. However, there is literature that clearly demonstrates that there is neither a total nor partial crowding-out from research subsidies[54]: and the RDTI should be even more efficient (see discussion in the following section).

It may be argued that the lumpiness of R&D is captured by averaging the additionality effects across a large number of organisations. However, this only illustrates the concern that assuming homogeneity amongst R&D-intensive businesses risks sidelining an industry sector whose characteristics diverge from those of other sectors claiming the RDTI.

> ***"Assuming homogeneity amongst R&D-intensive businesses risks sidelining an industry sector whose characteristics diverge from those of other sectors claiming the RDTI."***

52 Marianna Marino et al, "Additionality or crowding-out? An overall evaluation of public R&D subsidy on private R&D expenditure", *Research Policy*, 2016.
53 Centre for Science and Technology Studies, Leiden University, *Proceedings of the 23rd International Conference on Science and Technology Indicators: "Science, Technology and Innovation Indicators in Transition"*, 2018.
54 Hanna Hottenrott, Cindy Lopes-Bento and Reinhilde Veugelers, *Direct and cross-scheme effects in a research and development subsidy program*. Dűsseldorf Institute for Competition Economics, Discussion Paper No. 152, 2014, p.27.
55 Hottenrott et al, *Direct and cross-scheme effects in a research and development subsidy program*, p.31: See Table 2.5.
56 Hottenrott et al, *Direct and cross-scheme effects in a research and development subsidy program*, p.73.

## CALCULATING (FINANCIAL) ADDITIONALITY

The notion of a tipping-point is not reflected in the CIE Report, which assumes that the vast majority of R&D is covered under a substantive business-as-usual (BAU) case.[55] However, it is notable here that the vast majority of the RDTI is claimed by businesses outside the life sciences space. As the authors of the CIE Report note:[56]

> *Most R&D expenditure claimed under the programme (51.3 per cent) is registered as being related to engineering, and most of this is being conducted by large firms (in particular in the manufacturing and mining sectors). Research in information, computing and communication sciences accounts for 27.2 per cent (mostly by the finance sector), and all other research areas each account for 5 per cent or less.*

This is presumably reflected in the dataset underpinning the CIE report with weighting toward non-biotechnology use of the incentive. Certainly, this is reflected in the body of report, which states that consultation in life sciences appears to have been limited to one peak body.[57]

The number of biotechnology respondents to the survey is therefore unclear but would appear to be negligible. Looking at the taxonomy of the reported survey data, there is no specific category for life sciences or biotechnology, and the data are understandably dominated by mining, manufacturing and ICT.[58] In addition, consultations and data collection for this paper indicates that numerous life sciences organisations found the approach taken by the original survey questions somewhat clumsy and ill-aligned with their experience.

This is discussed further below but, before the life sciences sector is included in any revised tax arrangements, there should be a specific data collection and analysis of the true additionality of the life sciences sector.

**“Before the life sciences sector is included in any revised tax arrangements, there should be a specific data collection and analysis of the true additionality of the life sciences sector.”**

- Assuming homogeneity amongst R&D-intensive businesses risks sidelining an industry sector whose characteristics diverge from those of other sectors claiming the RDTI.
- The vast majority of the RDTI is claimed by businesses outside the life sciences space with the CIE Report finding the 51.3 per cent of the expenditure claimed under the RDTI being related to engineering; 27.2 per cent to research in information, computing and communication sciences; and all other research areas each accounting for 5 per cent or less.
- Given that the number of biotechnology respondents to the CIE survey is unclear but likely to be negligible and no specific category for life sciences or biotechnology, before the life sciences sector is included in any revised tax arrangements, there should be a specific data collection and analysis of the true additionality of the life sciences sector.

57 Hottenrott et al, *Direct and cross-scheme effects in a research and development subsidy program*, p.61.
58 Hottenrott et al, *Direct and cross-scheme effects in a research and development subsidy program*, p.179.

# Additional Additionality

The RIS acknowledges the concerns stated by CIE in their report, that:[59]

> *The two most crucial elements of the R&D TI (additionality and spillovers) turn out to be extremely difficult to empirically measure and evaluate.*

This is central to the concern that the available dataset inevitably lacks the granularity needed to capture the particular sensitivities of biotechnology research.

Beyond this, however, there is merit in expanding the definition of additionality to capture benefits beyond financial expenditure. Some of this is described in the CIE report in its discussion of spillovers, including the Productivity Commission's 2007 categories of:

- High-quality human capital development;
- Development of basic knowledge capabilities; and,
- Diffusion of new ideas among companies and others.[60]

These are notoriously difficult to quantify and, as CIE notes, there are transaction costs associated with knowledge uptake, even if it is a public good.[61]

In regards to this, the restriction of additionality to simple financial additionality is incomplete. Additionality should capture further benefits – some of which resemble spillovers, and some of which are internal – in order to provide a true and complete picture.

There is a range of arguments for this but, first amongst them, is that the prevailing approach to financial additionality is somewhat recursive.

This means that:

- Additionality only compares the volume of research which fits the definition of the RDTI with the increase in volume following access to the incentive [62,63]
- In doing this, it excludes other increases in investment within the organisation, or within the ecosystem in which the organisation operates, which are not captured in the tax-deductible frame.

Much of what is excluded comes under the headings of structural and behavioural change, which have investment, employment and other economically-relevant consequences.

An example of this is given in a recent paper from the Department of Industry's Office of the Chief Economist. This report builds on Akerlof's seminal work in 1970s on information asymmetry, noting that there is a share of market failure amongst firms – particularly small firms with limited history – due to lack of access to external funding.[64]

The conclusions from modelling associated with financial assistance from government (this includes both grants and tax incentives) is that there is a dual additionality effect:

- A dominant effect, that firms receiving government assistance are more likely to seek private financing; and,
- A residual effect, that companies are more likely with such assistance to receive this financing.[65]

Further, scale means that smaller businesses benefit more from these effects.

59 Australian Government Department of Prime Minister and Cabinet, Regulation impact statement: *Better targeting the Research and Development Tax Incentive*, p.2.
60 CIE Report, p.57.
61 CIE Report, p.57.
62 Or, in practice, the hypothetical reduction in research which would take place in the absence of current incentives.
63 There is also a contribution to deadweight loss here (see discussion later) whereby the tax rules may distort capital flows from non-deductible development to qualifying activity.
64 Sasan Bakhtiari, *Government financial assistance as catalyst for private financing*. Australian Government, Department of Industry, Office of the Chief Economist: Research Paper 6/2019, August 2019, pp.2-3.
65 Bakhtiari, *Government financial assistance*, pp.8-9.

Similar benefits are observed by Innovate UK for additionality from grant and other schemes, particularly that companies receiving assistance are 8-12 per cent more likely to survive with support than those not receiving that support. This is again clearer for younger, typically smaller, businesses.[66]

This is not, however, just a form of additionality for startups or other small organisations. There is strong support for the proposition that R&D tax benefits lead to more sustainable corporate growth across all organisations.[67] This is understandable as R&D is an essential part of inframarginal improvement in the face of competition.

This aspect of risk mitigation, which is seen in both access to finance and prospect of longevity, is not captured in the financial additionality measurement described previously and used to measure the additionality of the RDTI.

What is also not captured in current measures of additionality is the benefit consumed by other companies. This is similar to knowledge spillover but should also be included in additionality. The argument here derives from the general proposal (noted above) that the socially-desirable level of R&D exceeds what a profit-maximising firm will undertake on its own initiative.

The reason for this deficit, as first expounded by Kenneth Arrow in 1962, is that many of the outcomes of R&D are unavoidably appropriable: i.e. no intellectual property regime can be so watertight that a firm can completely capture its benefits without competitive use. Limited property rights, the need to release some information to use it productively and mobility of personnel lead to free riding.[68]

Free riding here is not undesirable, however, it is one reason why intellectual property systems insist on disclosure through publication, so that other companies can direct research where it is productive (closing duplicative research and building on established platforms). Despite the CIE's observation on transaction costs, this is a form of additionality which is expanded by the tax incentive as it is part of the incremental R&D output.

Returning to the question of access to capital, it is significant that R&D investment is pro-cyclical. This is due to the scarcity of capital in a downturn, during which larger businesses in particular tend to shed jobs and constrain innovation investment. Evidence here is that smaller companies are less affected by the cycle.[69] An illustration of this is given in Figure 3.[70]

> ***"An industrial firm trying to solve a local environmental challenge, most life sciences research is entirely portable. This is a strong argument for excluding this sector from the proposed changes to the RDTI."***

66 UK Government, Department for Business, Energy and Industrial Strategy, *The Impact of Public Support for Innovation on Firm Outcomes.* BEIS Research Paper Number 3, March 2017. P.12

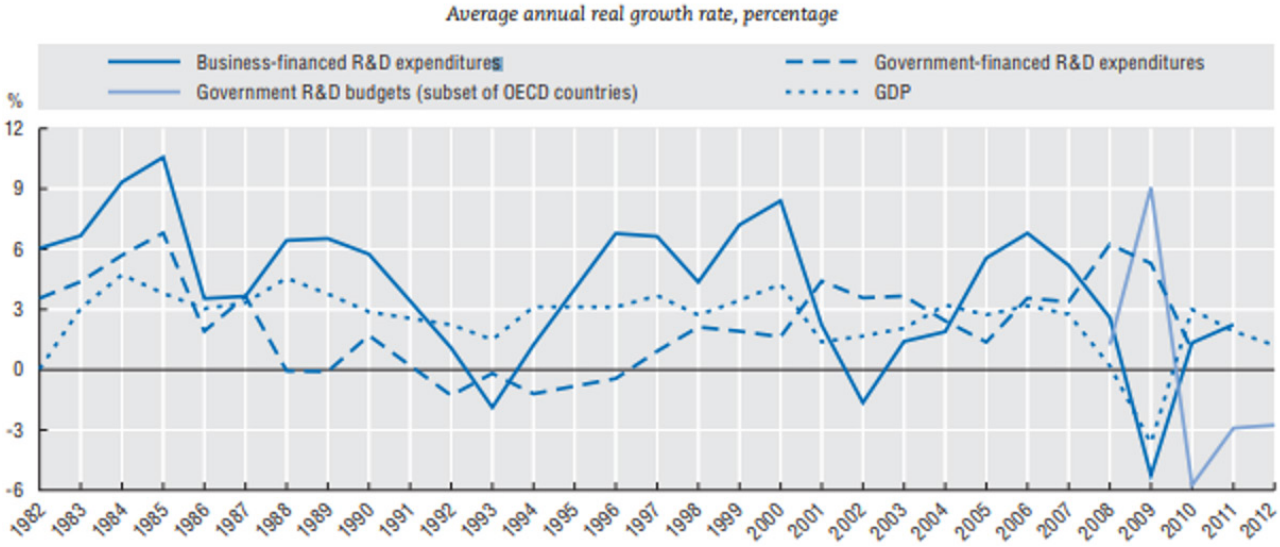
67 Dejan Ravšelj and Aleksander Aristovnik, "The Impact of Private Research and Development Expenditures and Tax Incentives on Sustainable Corporate Growth in Selected OECD Countries", *Sustainability*, 10:2034, 2018, p.10.

68 Dirk Czarnitzki and Koenraad Debackere, *Towards a portfolio of additionality indicators*, ECOOM KU Leuven, p.1: https://www.oecd.org /sti/081%20-%20Blue%20Sky%20ADD%20Paper%20Submitted.pdf Downloaded July 2019.

69 OECD, *OECD Science, Technology and Industry Scoreboard 2013: Innovation for Growth,* 2013, p.18: http://www.oecd.org/sti/scoreboard-2013.pdf Downloaded August 2019.

70 OECD, *OECD Science, Technology and Industry Scoreboard 2013*, p.26.

**Figure 3: R&D growth over the business cycle by source of financing, OECD area, 1982-2012**

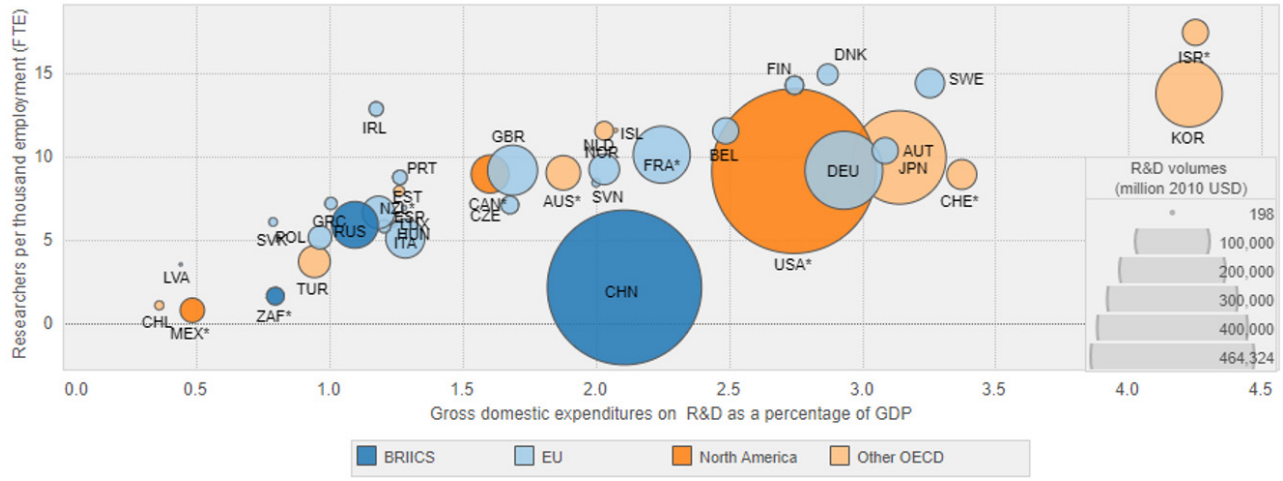



The relevance here, most clearly shown in the response to the most recent financial crisis, is that public incentives tend to act counter-cyclically as private funding sources contract. This implies that the relative additionality of public support, including tax incentives, varies according to the prevailing economic cycle. The need for additionality multipliers might be considered to account for this.

This is in essence a question of the efficiency of additionality, noting that it will vary not only by scale of investment but over time. In terms of the efficiency of additionality, Australia seems to sit at the midpoint of the OECD scale, with around a 12.6 per cent share of R&D funding by Government which is less than half of Canada or France. At the same time, Australia's performance is around the OECD median. Australia appears to be avoiding the substantial diminishing returns of some other jurisdictions.[71]

A snapshot of this middle position is illustrated in Figure 4.[72, 73]

**Figure 4: Human and Financial Resources Devoted to R&D, 2016**




71 Heike Belitz, *Support for private research and development in OECD countries on the rise but increasingly inefficient.* Deutsches Institut für Wirtschaftsforschung: DIW Economic Bulletin, Vol. 6, Iss. 8, p.107.

72 https://www.oecd.org/innovation/inno/researchanddevelopmentstatisticsrds.htm Downloaded August 2019.

73 * in chart indicates most recent data prior to 2016.

Drawing a line of best fit, what can be read from this is that the Australian rate of investment as a percentage of GDP is near the turn of the curve at which human resources input in R&D ceases to grow with greater expenditure. While this is not the only measure of performance, it suggests efficient R&D additionality at least for employment.

What this indicates is that there is important stability brought by public incentives and that Australia appears to be balancing this by avoiding overinvestment.

Behavioural additionality adds further to these effects. Looking at a sample of companies receiving R&D tax credits in Belgium, Neicu et al identified a number of firm-level outputs (not spillovers) associated with changes in firm decision-making. These are:

- Going beyond scale and speed (marginal effects), tax credits appear to have more far-reaching effects, such as additional projects, including those with greater technological challenges;
- Tipping the R&D balance more toward actual research; and,
- Historical experience, based on OECD research in Finland of more long-term investment and greater risk appetite.[74]

The authors here also observe that these effects are stronger for tax-credits than for direct subsidies. This may reflect a range of issues, including diversification benefits of an open scheme and the tendency of subsidies to attach to BAU development, but it supports the Australian bias towards 85 per cent of Government support through the RDTI.[75]

The benefit of tipping the scale within companies to *research* rather than *development* is also important to additionality. There is greater observed 'additionality power' for research[76] meaning the ability of public funding to address market failure, which is the central argument for the RDTI.

The issue of export additionality should also be noted. The evidence here shows that public support for innovation will lead to an increase in exports, which has an additional economic effect. Importantly, export additionality is greater for novel products,[77] which in turn increases the value proposition for the RDTI when applied to research rather than development.

Finally, an argument for greater additionality which is specific to the life sciences is proposed. Whereas engineering and mining R&D have the potential to increase productivity or stimulate demand for employment, life sciences research transcends these benefits. Whereas most industry captures benefits in increased activity and income, biotechnology also offers expanded public welfare outcomes.

Accordingly, additionality for this sector should also include:

- An extra weighting for the health benefits (and their economic flow-ons) which are consequent to biotechnology research; and,
- A further weighting for such activity being retained in Australia, despite strong competition from other markets.

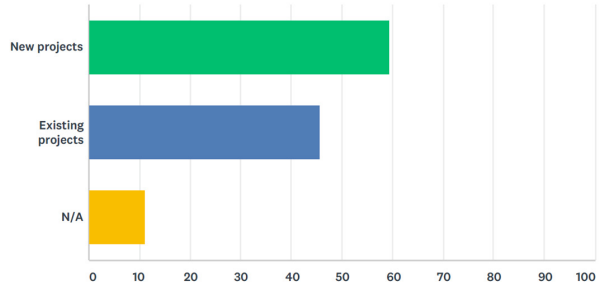
The latter point is because of the notorious difficulty in retaining life sciences R&D outside the countries in which global biotechnology companies and large research universities are headquartered. **Unlike, for example, an industrial firm trying to solve a local environmental challenge, most life sciences research is entirely portable. This is a strong argument for excluding this sector from the proposed changes to the RDTI.**

74 Daniel Neicu, Peter Teirlinck and Stijn Kelchtermans, "Dipping in the policy mix: do R&D subsidies foster behavioural additionality effects of R&D tax credits?", *Economics of Innovation and New Technology*, 2 September 2015: https://www.tandfonline.com/doi/abs/10.1080/10438599.2015.1076192 Downloaded July 2019.
75 Datum from Belitz, *Support for private research*, p.107.
76 Hottenrott et al, *Direct and cross-scheme effects*, p.27.
77 Mark Freel, Rebecca Liu and Rammer Rammer, "The export additionality of innovation policy", *Industrial and Corporate Change*, 2019, p.13.

# Expected Firm Behaviour

The purpose of the recent AusBiotech survey was to identify how relatively small claimants of the RDTI will react to potential changes in the tax rules as well as gauging what actions companies might take in the event of increased availability of R&D funding and other issues.[78] This is highly disparate, as the life sciences sector is notoriously heterogeneous in focus, scale and strategy, but Figure 5 demonstrates where life sciences companies would allocate additional R&D funds.

**Figure 5: Where would Australian life sciences companies allocate any increase in R&D funds?**

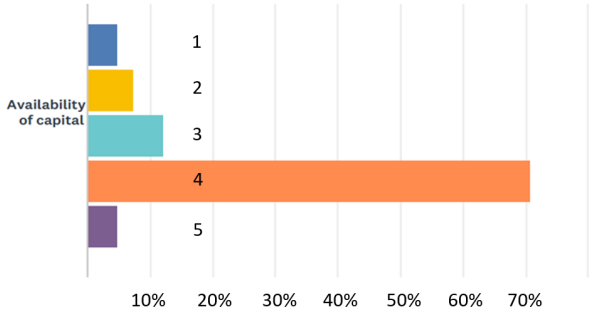



While this does not reflect specific quantities, it shows the general approach to additionality in the biotechnology marketplace. Some 89 per cent of respondent organisations would use any increase in funding for R&D activity, with a substantial majority (59 per cent) applying it to new projects. The application to existing projects would lead to either extended activity or shorter timelines, improving productivity.[79]

**The converse of this is that any contraction in R&D funding would likely lead to reduction in funding of new or existing projects, with an attendant loss of additionality and spillovers.**

Through the same survey, respondents were asked to rate the impact of some 19 factors and how they affect the willingness to undertake R&D in Australia. On a 1-5 scale, the most stark factor is availability of capital, which is demonstrated in Figure 6.

**Figure 6: Importance of availability of capital in the R&D allocation process**




Here, over 75 per cent of respondents rated this a 4 or 5 on the scale provided where 5 was the highest available score. This dominates company tax, other government factors, intellectual property issues, risk questions and competing overseas opportunities. The strength of this response merits deeper investigation as part of the RDTI reform process.

**“The converse of this is that any contraction in R&D funding would likely lead to reduction in funding of new or existing projects, with an attendant loss of additionality and spillovers.”**

78 The survey was circulated to 128 members of AusBiotech representing health and medical research and was also highlighted in AusBiotech’s enewsletter. Complete responses were received from 37 organisations and individuals.

79 These data exceed 100 per cent in total because some firms would split the increased funding between both new and existing projects.

80 This apparently varies between projects, with individual firms attributing some decisions to the incentive, and some made irrespective of it.

The sensitivity of capital availability and cost is discussed further below, but it is worth noting that the RDTI rate is a critical factor in capital access.

Further reinforcing this, respondents to the survey noted that the proposed changes to the RDTI will have a material effect on their R&D activities, with:

- 63 per cent advising that the RDTI materially influenced the decision to undertake the R&D;[80]
- 61 per cent of respondents noting that it would affect the sustainability of their businesses;
- 57 per cent advising that changes would impact on the amount of R&D their businesses undertake in the future; and,
- The mean level of reduction in R&D anticipated is 29 per cent.

While the data from the AusBiotech survey are insufficiently granular to interpolate how much change there would be to R&D activity in the life sciences sector, the following conclusions can be reached: that there is a substantial level of additionality, as organisations would reduce activity if the RDTI were constricted; and that there is a substantial proportion of biotechnology companies whose actual existence would be threatened by the changes.

This is substantially different from the sanguine picture of the environment after RDTI changes imagined in the RIS. In addition, it indicates that life sciences companies differ from the general case.

This is certainly borne out when comparing these data to those captured in the CIE Report. Whilst 63 per cent of respondents to the AusBiotech survey indicated that the RDTI materially influenced the decision to undertake their current level of R&D, the CIE Report found that only about one-third of R&D spending decisions (weighted by R&D expenditure) were materially influenced by the RDTI programme.

In fact, only 35 per cent of all respondents to the CIE survey reported that RDTI materially influenced their R&D with this percentage rising to 54 per cent for SMEs.

The fact that 61per cent of respondents to the AusBiotech survey indicated that the proposed changes to the RDTI would both affect their expenditure on research and development and threaten the sustainability of their businesses is, however, reflected in the CIE Report which found "compelling evidence from consultations and interviews that small start-ups, particularly in the research-focused biological and medical areas that receive a cash refund from the offset, rely on it to be able to continue their research".[81] In addition, consultations for that Report reported that start-up medical firms would not survive without the RDTI.[82]

One of the problems identified in responses to the AusBiotech survey is that the proposed changes to the RDTI will also potentially lead to a vicious cycle. The anticipated impacts of the changes are expected to be felt most keenly in:

- Future capital flows with 53 per cent of respondents rating this as either significant or very significant;
- Future scale of R&D where 56 per cent rated this as either significant or very significant; and,
- Future scope of R&D where 53 per cent rated this as either significant or very significant.

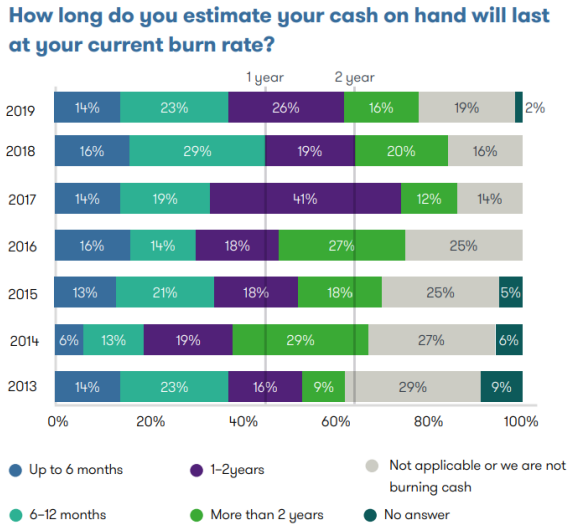
These are recursive effects, which will limit innovative output in the short-term and reduce the critical mass of activity and researcher opportunities in the medium term. It will further exacerbate the gap between grant-based basic research and commercially-funded development, acting to undermine Australia's enviable reputation as a life sciences powerhouse.

81 Centre for International Economics, *R&D Tax Incentive Programme Review*, prepared for the Department of Industry, Innovation and Science, 29 March 2016, p. 135.
82 CIE Report, p. 163.

# Cost of Capital

Prevailing capital expectations for Australian biotechnology companies can be derived from the expected burn rate of currently available funding as demonstrated in Figure 7.[83]

**Figure 7: Estimated Burn Rate for Australian Life Sciences Firms, 2013-2019**



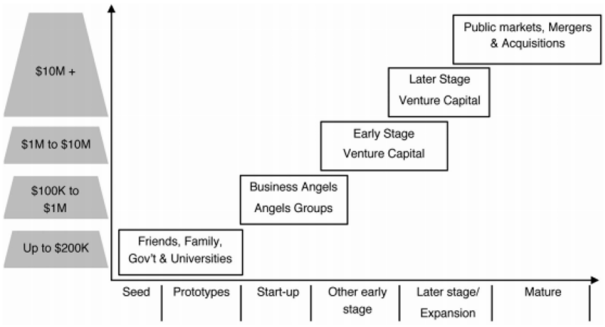

From this, some fluctuation over time can be observed. Further, around 20 per cent of companies at any given time are not burning cash, so presumably are either self-sustaining or have predictable medium-term finance capabilities or are in between or not undertaking clinical trials presently.

The weighted average cost of capital (WACC) for biotech firms is expected to be bimodal, between:

- A small group of larger and older businesses, who have a mix of equity and debt; and,
- The majority of life sciences research companies, whose capital sources are purely equity.

In the latter case, there is a typical sequence of capital sources, shown as follows in Figure 8.[84, 85]

**Figure 8: Funding chain by stage of development and size of investment**




Here emergence from typical network sources, through commercialisation funding, can be observed. Acquisition of monoline startups is much more common than maturity to new listed entities. This in no way resembles the dominant form of R&D currently being compensated by the RDTI, which is development and refinement of products in already mature companies with multiple capital sources.

Earlier in this document, the issue of information asymmetry and its effect on capacity to obtain financing was noted. This is particularly acute in the venture capital space, in two directions:

1. The persistent uncertainty of investment into biotechnology startups, which are in the main more likely to fail than succeed; and,
2. The limited understanding, which founding scientists traditionally have of capital markets, giving them limited capacity to negotiate.

The consequences of this are that: venture capital (VC) is a risky investment, due to prospect of failure and medium-term illiquidity of any investment; and it is very expensive capital,[86] i.e., founders are

83 AusBiotech, *Biotechnology Industry Position Survey 2019,* p.13.
84 P Lehoux, F A Miller and G Daudelin, "How does venture capital operate in medical innovation?", *BMJ Innovation*, Vol. 2, 2016, p.112.
85 Figures are in CAD. Current exchange rate is CAD1= AUD1.11. Regardless of exchange rate, the sequence is common.
86 P Lehoux, F A Miller G Daudelin, "How does venture capital operate in medical innovation?", *BMJ Innovation*, Vol. 2, 2016, p.112.

exchanging much more of their equity for a given level of investment than would occur in the case of perfect symmetry or in the presence of alternative capital sources.

While the data gained from AusBiotech's recent survey is limited, it is clear that government and tax factors as well as the availability of capital are dominant features of the R&D decision-making process.

As with most investors in intellectual property, VC tends to treat biotechnology on a portfolio basis, expecting outsize returns on a fraction of investments in order to compensate for the losses in others. While the pricing behaviour of VC firms is sometimes impugned, there is no credible alternative model and startups will only have access to other capital sources where they can provide security from less risky assets.

This is not a one-time issue at the initial capitalisation of a biotechnology venture. Because there are likely to be multiple funding rounds prior to any sales, organisations do not have the normal advantage of releasing trading information, but must 'manage sentiment' through the release of indicative progress, such as IP registrations, licensing agreements and the like.[87]

When the proposed changes to the RDTI are considered, a reduction in tax deductibility has an effect on the cost of capital, again from two perspectives:

1. Capital used by the R&D firm is less efficient, so more will need to be sought, for a higher price (in terms of equity exchanged); and,
2. For the VC investor, the reduction in the efficiency of capital makes the investment slightly less attractive, so this probably also compounds the price.

The outcome is that R&D – particularly in riskier industries – is a less attractive destination for the initial capital sources of self-funding and family capital, so less activity may take place. VC firms, and particularly those with limited competition, may not share this perspective as their interest lies in return on investment, so the higher cost of capital is potentially a positive.

This issue is magnified in Australia, because again, it is not a natural destination for either biotechnology commercialisation or VC activity, so there is less competition amongst providers of capital. Consequently, the price of VC funding may be higher than in other markets which may in turn be a reason for innovation departure at critical stages.

The literature on this question shows that even in a market as large as the United States, there is spatial concentration of the two fundamental inputs of life sciences development: ideas and capital. This is recursively reinforced by knowledge spillovers, which tend to be shared more by proximate companies.[88]

The problem of access to capital is further affected by the sheer scale of R&D costs in the life sciences. This is driven by the twin goals of proof of efficacy and proof of safety, for which high and expensive bars are set by agencies, such as the Food and Drug Administration (FDA) in the United States and the Therapeutic Goods Administration (TGA) in Australia.

If the example of a new pharmaceutical is considered, for example, a recent estimate puts the cost of development to final approval at somewhere between US$1395 million and US$2558 million,[89] or A$1992 million and A$3654 million.[90] This figure is only likely to increase over time. If this is considered from a VC or medicines company perspective,

87 Kean Birch, "Rethinking Value in the Bio-economy: Finance, Assetization and the Management of Value", *Science, Technology & Human Values*, Vol. 42:3, 2017, p.480.
88 Walter W Powell et al, "The Spatial Clustering of Science and Capital: Accounting for Biotech Firm-Venture Capital Relationships", *Regional Studies*, Vol. 36:3, 2002.
89 Henry G Grabowski and Ronald Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs", *Journal of Health Economics*, February 2016, p.31.
90 2013 dollars, Nominal exchange rate of AUD1=US$0.7.

the figure is even higher when the sunk costs of unsuccessful investigations are included.

It is notable that amongst the measures which do assist with formation of clusters are subsidies and tax exemptions.[91]

All of these issues: VC capital costs; high cost of development; and clustering effects are more significant in the life sciences sector, because it is upstream from much more rigorous market entry barriers than other innovation.

This is a strong argument to distinguish biotechnology research from other R&D when considering changes to the RDTI.

91 Mikhail Yakovlevich Veselovsky, "Development of Financial and Economic Instruments for the Formation and Management of Innovation Clusters in the Region", *Mediterranean Journal of Social Sciences*, Vol.6:3, May 2015, p.120.

# Reproducibility

A range of risks have been noted throughout this report, but one which is somewhat peculiar to the life sciences is the issue of reproducibility. To illustrate this, a comparison might look at:

- R&D for the refinement of mining machinery, which can be improved incrementally, but has a relatively predictable outcome; with,
- Investigation of the manipulation of a newly-identified gene to treat what is hypothesised to be a susceptible cancer.

The issue of reproducibility, that goes to the question of reliability of scientific endeavour as an investment choice, is currently fraught. It is described in some quarters as a 'crisis of reproducibility', characterised by 'over-interpretation' of difficult data.[92]

This is an issue that is being addressed by better training and common standards and is a global concern. It is a cultural issue, which is assisted by collaboration, but mostly requires more careful use of statistical methods.[93]

This matters for two critical reasons:

1. It is one source of the concern about information asymmetry that makes capital cost so high. Greater confidence in reported research outcomes removes a major source of uncertainty; and,
2. Money is wasted.

A recent consideration of this problem suggests that, using 2012 data from the United States, some US$56.4 billion was spent on preclinical life sciences research of which only $US28 billion was directed to reproducible research.[94]

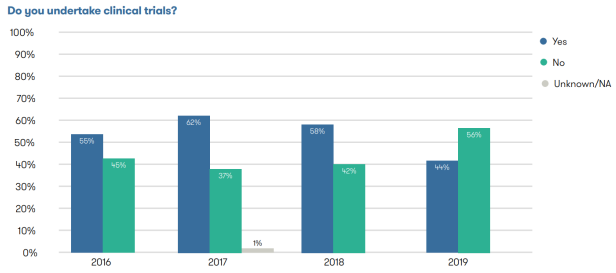
The argument here is not that life sciences research is an unreliable field, but rather that there are global market characteristics outside the control of well-intentioned Australian researchers, which have the potential to further increase the problem of the cost of capital.

92 Marcus R Munafo et al, "A manifesto for reproducible science", *Nature Human Behaviour*, 1:0021, 2017, p.1.
93 Marcus R Munafo et al, "A manifesto for reproducible science", *Nature Human Behaviour,* 1:0021, 2017, p.2.
94 Leonard P Freedman, Iain M Cockburn and Timothy Simcoe, "the Economics of Reproducibility in Preclinical Research", *PLOS Biology*, June 9, 2015, p.2

# Quarantining Clinical Trials v. Quarantining Life Sciences

The proposal to separate clinical trials from other life sciences R&D presents unquantified risks. First, looking at the biotechnology sector in Australia, the percentage of organisations – all of whom undertake some R&D – who undertake clinical trials changes from year to year. This is demonstrated in Figure 9.[95]

**Figure 9: Share of Respondents Undertaking Clinical Trials, 2016-2019**




The radical shift in clinical trial share from the prior three years to the current year may reflect the expected change in tax treatment, and thus cost of capital, under the proposed changes to the RDTI. This requires further investigation but, if it were the case, it would lead to a range of concerns including:

- First, it would suggest a likely deadweight loss which would only occur in this one sector, as a particular form of R&D is preferred and thus capital flows are distorted toward it. This may reduce efficiency by shifting investment without increasing productivity;
- While, as noted above, there is greater additionality associated with research rather than development, clinical trials are not the full research componentry of life sciences. Pre-clinical and benchtop research is the bedrock of any biotechnology innovation and the separation of clinical trials may foster an unnecessary and unproductive split between research activities; and,
- Noting the commentary above on cost of capital, there is a potential interruption to the milestones in research funding, where some elements have a lower capital price than others.

These issues are compounded by the lack of clarity as to the definition of a clinical trial for purposes of the RDTI. Key questions here include:

- Are the entire salaries of researchers employed in clinical trials incentivised or only the component they spend working on the trials themselves (not, for example, reporting, undertaking administration or applying for funding)?;
- Are the salaries of project administrators overseeing funding, procurement and staffing to be included?;
- Is a percentage of overhead able to be hypothecated to clinical trials and, if so, at what rate?;
- What percentage of plant is applicable to the clinical trial?; and,
- Is the exclusion only applicable from the commencement of the trial or does it include the extensive preparatory work such as planning, fundraising and ethics approvals, which precede the trial?

95 Ausbiotech, *Biotechnology Industry Position Survey 2019,* p.9.

## QUARANTINING CLINICAL TRIALS V. QUARANTINING LIFE SCIENCES

Regardless of the answers to these questions, they present a significant degree of complexity to participating companies and on two fronts. First, there will be some transaction costs associated with delineating and managing the separation of clinical trial and non-clinical trial R&D for tax purposes.

Secondly, there will remain some uncertainty, given the heterogeneity of life sciences endeavours, their clinical trial levels and the unpredictability of tax interpretation. It is clear from the recent AusBiotech survey that there is no single R&D pathway and the impact of tax changes may be highly variable from one company to the next.

Given the positions articulated above regarding the greater additionality of biotechnology research and its relatively small share (part of the 5 per cent 'other' covered by the RDTI), a better path forward would involve protecting the life sciences sector under the current rules, including for future investment.

Little evidence exists of substitution of capital between industrial and IT research, which is designed to improve the economic and social benefits of industry and IT, and that in the life sciences sector. Consequently, there would be trivial or no distortion as a result of this exclusion.

# Intensity and Tax Issues: A Rethink Required

Prior discussion in this paper has focused on concerns about the applicability of additionality modelling to the life sciences sector in Australia. Areas of particular concern in this regard include the lack of specific data available regarding biotechnology; literature on alternative and expanded measurement methodologies; and the idiosyncrasies of the life sciences sector, amongst others. These issues raise concerns about the additionality modelling utilised to inform the proposed changes to the RDTI and its relevance to the life sciences sector. These primarily focus on additionality.

On the issue of the intensity proposal, the RIS found:

> *Compared to companies with lower R&D intensity, [more intense] claimants make more efficient use of scarce R&D resources such as skilled labour and specific capital equipment and are more likely to be induced to increase their investment in R&D (i.e. generate increased additionality and thus produce greater spillover benefits).*[96]

This conclusion is not supported by the available literature or the CIE report. Rather, it seems to be an artefact of the view that larger companies, which are likely to be more mature and less intensive, display lower additionality. The latter conclusion is also contestable and, in any case, ignores the ecosystem issues described above.

Further, it contravenes broader underlying economic theory in two ways:

- The implication that less-intensive companies have a lower incentive to maximise their productivity in one area of endeavour, which is their R&D; and,
- It would need to be argued that somehow the likelihood of market failure is linked to R&D intensity, for which there is no clear evidence.

Further, the submission of Xenith IP makes a valid argument regarding the asymmetry of intensity measures as applied to Australian and foreign businesses.[97] The argument here is that:

- A large Australian multinational undertaking R&D in Australia may have low intensity, because its headquarter operations may dominate its R&D activities for tax purposes; whereas,
- A foreign multinational purely operating an R&D subsidiary in Australia will locally appear to be highly intensive.

This is equally an issue for the application of additionality, to argue that scale thresholds should limit access to the RDTI. It permits competitive tax planning by foreign companies yet, at the same time, this will tend to magnify the advantages of foreign multinationals headquartered in countries with lower overall tax burden.

This is not an easy problem to solve as multilateral and plurilateral trade agreements prohibit differential tax treatment to compensate for such issues.

**While there is not an easy solution, it is important to illustrate the risks inherent in changing the RDTI without understanding the impact on different sectors. Comparative tax advantages already exist for foreign companies, but these must not be unnecessarily magnified and the sustainability of the life sciences sector and its ecosystem must be preserved.**

96 Department of Prime Minister and Cabinet, *Regulatory Impact Statement*, p.3
97 Xenith IP Group Ltd, Submission on Consultation Paper: *Reforming the R&D Tax Incentive*, 26 July 2018, pp.15-16

## INTENSITY AND TAX ISSUES: A RETHINK REQUIRED

**While there is not an easy solution, it is important to illustrate the risks inherent in changing the RDTI without understanding the impact on different sectors. Comparative tax advantages already exist for foreign companies, but these must not be unnecessarily magnified and the sustainability of the life sciences sector and its ecosystem must be preserved.**

## Disclaimer

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## Evaluate

Evaluate was formed in September 2016, to bring fresh thinking to policy and economic questions, particularly those in the social sphere.

Our particular goal is to identify long-term solutions to ensuring the sustainability of Australia's admirable social compact, including universal access to healthcare and education, and the supply of aged care, housing and other social infrastructure.

Our approach is based on a traditional microeconomic toolkit, moderated by the knowledge that social services are accessed by people with a vast variety of experiences, needs and resources. Consequently, we have no bias towards either public or private supply of services, noting that the access and welfare needs of different Australians typically require a mix of both.

The Principals of Evaluate are experienced professionals, and we complement this with external expertise where appropriate.

www.evaluate.net.au

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## About AusBiotech

AusBiotech is Australia's life sciences organisation, working on behalf of members for more than 30 years to provide representation and services to promote the global growth of the Australian life sciences industry. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), digital health, food technology and agricultural sectors.

It has representation in each Australian state, providing a national network to support members and promote the commercialisation of Australian life science in national and international marketplaces.

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