THE UNIVERSITY OF SYDNEY AND AUSBIOTECH A PROJECT TO IMPROVE INDUSTRY–UNIVERSITY PARTNERSHIPS

Accelerating Health and Medical Research Commercialisation in Australia

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+ MAIN REPORT

THE UNIVERSITY OF SYDNEY

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

A joint initiative between The University of Sydney and AusBiotech

A national approach for the global stage

The University of Sydney and AusBiotech Project

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EXECUTIVE SUMMARY

This project is a joint initiative between The University of Sydney, Faculty of Medicine and Heath (FMH), The University of Sydney Business School, and AusBiotech.

The project brings together cross-disciplinary expertise to build a fundamental understanding of the factors that make industry partnerships work. The objective is to develop a framework to inform and guide partnerships between universities and the biotech sector, and subsequently improve the translation and commercialisation of health and medical research in Australia.

Close to 70 prominent stakeholders from across industry (including biotechnology, medical technology, and pharmaceuticals), consultants, independent research organisations, academia, university operations and Government were invited to contribute to the project via two phases of stakeholder engagement. The first phase consisted of one-on-one interviews with stakeholders and project leads, Holly Pobjie and Alex Best, to gain stakeholders' real-world insights and experience with industry-university partnerships for the commercialisation of research. The second phase brought together key stakeholders to participate in a half-day virtual roundtable event involving an interactive discussion on best practice in successful industry-academic collaborations, and stress testing of proposed recommendations based on key themes identified through the first phase of stakeholder engagement.

Overall, 49 invited stakeholders (72%) volunteered to participate in the one-on-one interviews, and 38 (56%) participated in the virtual roundtable event. This equates to approximately 165 hours of stakeholder time given voluntarily to support this project.

Through synthesising existing information, previous papers, and the themes and insights gained through the stakeholder engagement process, ten recommendations (outlined on the following page and explained in further detail later in the report) have been developed, aiming to address the key barriers to successful industry-university partnerships and subsequently enhance research translation and commercialisation outcomes in the health and medical sector.

The core themes, or barriers to successful partnering, that these recommendations are aiming to address, based on feedback gained through the stakeholder engagement process, are assessment of value between university and industry partners; optimising translational research and technology transfer offices (TTOs); commercialisation as part of an academic's career; and proof-of-concept (PoC) funding.

Additionally, the report outlines two specific proposals for implementation in the near-term at The University of Sydney, the MBA-FMH Seed Fund, and an Industry-Track enabling The University of Sydney academics to explore commercial applications of their research. The aim of these proposals is to continue to support the collaboration between FMH and The University of Sydney Business School, thereby giving academic researchers access to business expertise, as well as adjusting the standard academic employment conditions to support researchers in exploring the promising commercial applications of their research.

While recommendations, and subsequent proposals, have been proposed in the context of The University of Sydney's current processes and landscape, the aim is to be broadly and generally applicable across the industry. Many of the barriers identified are evident across Australia as a whole, and not specific to any one institution or organisation. Additionally, several of the recommendations would require significant collaboration and cross-commitment across the sector to implement this framework for successful industry-university partnerships and improve the output of Australian universities in the post-COVID period.

Recommendations (Summarised)

RECOMMENDATION 1 – *PoC FUNDING:* Create a national University proof-of-concept (PoC) Scheme to support both clinical and commercial PoC activities.

RECOMMENDATION 2 – *INCENTIVISE:* Adjust standard Enterprise Bargaining Agreements (EBA) and Key Performance Indicators (KPI) for academic researchers who are seeking to explore the commercialisation potential of their research project/specialty.

RECOMMENDATION 3 – *GLOBAL PLACEMENTS:* Industry fellowships should consider global placements in order to access international research and development (R&D) infrastructure and maximise the learning opportunity.

RECOMMENDATION 4 – *UPSKILL:* Improved training and professional development opportunities for commercialisation offices within Australian universities.

RECOMMENDATION 5 – *COMMERCIALISATION INSTITUTE:* Partner with AusBiotech on the development of an Australian Commercialisation Institute (ACI) to leverage expertise by forming strategic partnerships to access more sophisticated insights into the commercial potential of university research.

RECOMMENDATION 6 – *SECONDMENTS INTO INDUSTRY:* Secondments for Tech Transfer Offices (TTO) staff within private equity/venture capital firms to understand their approach to valuing pre-clinical invention disclosures/intellectual property (an extension of current programs focused on researchers).

RECOMMENDATION 7 – *TRACK COMMERCIALISATION:* Develop metrics to assist TTOs in tracking their commercialisation progress, complemented by standard term sheets outlining baseline terms and conditions to streamline the negotiation of licence, option or assignment.

RECOMMENDATION 8 – *INTEGRATE BUSINESS KNOW HOW:* Additional clarity on the TTO contacts and processes, such as publicly available information on baseline terms and conditions for standard agreements, and general information on approaches to IP and equity structuring.

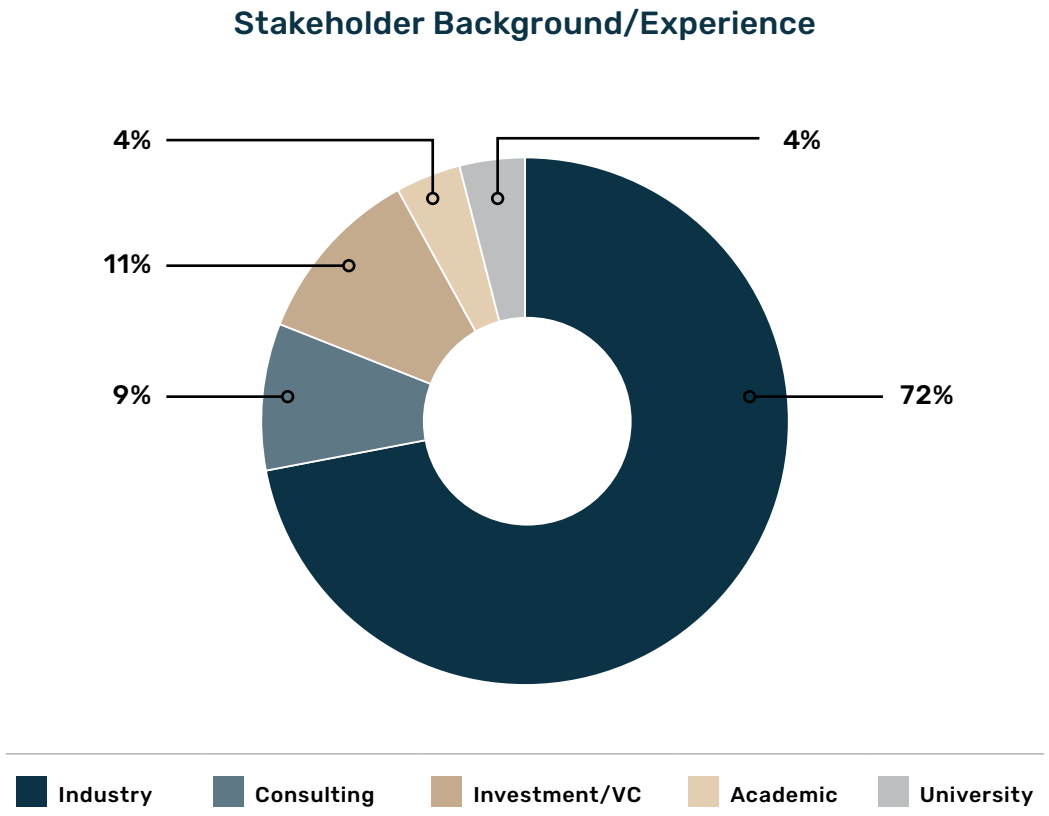
RECOMMENDATION 9 – *ATTRACT THE RIGHT TALENT:* Access the global pipeline of TTO talent by creating opportunities commensurate with those in the US and UK. This may require re-evaluating the optimal personnel size and resourcing requirements for Australian TTOs, complemented by an Australian association of university technology managers with an annual forum for sharing ideas, trends, and best practices.

RECOMMENDATION 10 – *FREEDOM TO PUBLISH:* Industry should ensure publication requirements can be accommodated as part of industry-funded research, as academic journal publication remains an important criterion for grant funding and career progression.

STAKEHOLDER ENGAGEMENT

The first phase of stakeholder engagement undertaken as part of this project involved 49 interviews with key stakeholders from across industry (including biotechnology, biomedical, pharmaceutical), consultants, university operations, investment and venture capital, and academia. The breakdown of stakeholders interviewed, by background, is shown in Figure 1 below. As it shows, during this first (and the subsequent second phase described in the following section), the majority of stakeholders we engaged came from an industry background. It has been noted that an additional phase is warranted. Following on from the publication of this report and circulation to industry stakeholders, the recommendations and proposals should be tested within a broader academic stakeholder group, to ascertain their appetite and feasibility to adopt them.

FIGURE 1: *Breakdown of stakeholders participating in one-on-one interviews by background/experience.*



The purpose of the interviews was to gain insights into stakeholders' real experiences in partnering with universities and identify potential barriers that exist to successful and mutually beneficial partnerships. Stakeholders were asked to discuss the reasons they seek to partner with universities, what the expectations are when partnering, and what some of the common barriers are to successful partnerships that they have experienced.

From these interviews, the qualitative data collected was analysed to determine the key themes that should form the recommendations and proposed outcomes for this report. The identified areas, further consultations and the recommendations stemming from these interviews are outlined in the following sections.

THE UNIVERSITY OF SYDNEY – AUSBIOTECH HOSTED ROUNDTABLE

The University of Sydney and AusBiotech jointly hosted a virtual roundtable on Friday 15 October 2021, which constituted the second phase of stakeholder engagement undertaken as part of this project. The roundtable, titled 'Industry-University Collaboration in Medicine and Health – Pathways to Accelerate' was attended by 38 representatives from The University of Sydney, AusBiotech, the biotechnology, biomedical, pharmaceutical, and other relevant sectors, including 30 who had previously participated in a one-on-one interview as part of the first phase of stakeholder engagement.

The roundtable included presentations from Professor Robyn Ward, Executive Dean and Pro-Vice Chancellor Medicine and Health, The University of Sydney, and Michelle Burke, Director (2012-2021), Chair (2020-2021), AusBiotech, as well as an interactive discussion on best practice in effective industry-academic collaborations in medicine and health, hosted by Dr Dean Moss, Chief Executive Officer, UniQuest.

Following this discussion, the proposed recommendations arising from the first phase of stakeholder engagement were stress tested with participants, via discussions on the four key areas to be addressed, identified during the phase one interviews: assessment of value between university and industry partners; optimising translational research at TTOs; commercialisation as part of an academic's career; and PoC funding.

The key insights and action areas stemming from this roundtable are summarised below:

A MISSION STATEMENT PRIORITISING RESEARCH COMMERCIALISATION

Participants highlighted the importance of universities having a mission statement which acts as a 'north star' ensuring research commercialisation is a priority at Vice-Chancellor and University Council level which is then integrated into university practices via the appropriate partnering across faculties. In order to be sustainable, the mission requires a suitable long-term runway to create time for outcomes to be delivered. For this reason, KPIs relating to research commercialisation should not necessarily be focused on the number of deals completed or the revenue generated from licensing/royalties or spin outs but rather by research 'impact' which could include increases in size and role of local industry and an increase in the number of entrepreneurs. Revenue can still be an important metric but there needs to be acceptance that it requires a long lead time, as set out in the Survey of Commercial Outcomes from Public Research (SCOPR).

Universities could create this sense of mission via an Entrepreneur in Residence within relevant faculties or operating across faculties. This could offset the inherent risk aversion of universities which informs the way they engage with industry, particularly when negotiating commercial agreements. It is also necessary for universities to more formally incorporate business expertise into their health and medical research faculties with business and law schools.

THE NEED FOR GREATER POC FUNDING

Reiterating one of the core findings from phase one of the stakeholder engagement process, there was agreement amongst roundtable attendees that lack of PoC funding support was an overarching problem in this space. However, the discussion highlighted that the definition of PoC is very important, and it can refer to different things depending on the context. For example, there is a need to consider both 'technical' PoC and 'clinical' PoC (discussed in further detail below).

Participants noted that there is a significant amount of potential financing available in the Australian and international ecosystem to address the first valley of death and address the PoC funding challenge if the value proposition for this stage can be successfully articulated. This can be supported by strategies to increase biotechnology literacy for investors and programs that can build greater connections with international investment funds.

It was observed that the value proposition of early stage (pre-clinical) research and the potential return on investment needs to be more clearly articulated and the opportunities for investment more widely shared. It was noted that a coherent Australian industry policy which outlines a co-ordinated national innovation ecosystem could build business confidence and contribute to increases in translation outcomes.

A VIRTUAL COMMERCIALISATION INSTITUTE

There was some support for the concept of virtual commercialisation institute where researchers could access best-in-class advice in technical, clinical, and commercial areas (for example, Life sciences version of the Australian Institute of Sport (AIS). Critically, this would need to be on a national level to be done at scale. There are already a range of successful programs that are making some impact on this problem.

An alternative design proposed was a National Incubator Model with multiple nodes and entry points for industry and researcher engagement. The revenue model to support this institute would need further discussion. A sustainable funding model is critical for robust outcomes (similar to ANDHealth and Cicada).

EFFECTIVENESS OF AUSTRALIAN TTOS

Participants identified the need to critically assess whether current recruitment model, salary points, and freedom to operate are attracting top-tier TTO talent. The increased use of competency tables in recruitment processes was raised as a potential solution in this regard. This is also necessary to address the misalignment in approaches to valuation. Researchers also need to improve their understanding of this process.

VALUATION CHALLENGE FOR EARLY-STAGE RESEARCH

Participants highlighted the disconnect between industry and researcher expectations regarding the value of pre-clinical research. Industry participants noted the importance of researchers receiving feedback from potential investors at an early stage so challenges in the commercialisation journey could be identified and addressed. If this feedback was not received at an early stage the researcher may progress the research in a direction which reduces the likelihood of a commercialisation outcome.

This disconnect is exacerbated by the absence of an objective valuation methodology which would enable both sides to have a framework for discussing commercial terms. This was also an issue that was raised as part of the Higher Education Research Commercialisation IP Framework consultations. Alternative pre-seed strategies were discussed as a solution to the valuation challenge, including convertible notes and SAFE notes. Both methods are emerging as a more founder friendly technique for postponing the valuation issue until it is at a point where a more accurate assessment can be made.

AUSBIOTECH'S 'BIOTECHNOLOGY BLUEPRINT: A DECADAL STRATEGY FOR THE AUSTRALIAN'

AusBiotech's Biotechnology Blueprint was also discussed with participants noting that recommendations arising from this report could be complementary to AusBiotech's vision of a decadal plan that builds both a thriving ecosystem and develops a sovereign capability for biotech in Australia.

Strong areas of alignment between the two initiatives include:

- The need to grow the overall pool of funders and understand their 'return vs risk' appetite for pre-clinical investment.
- Leveraging personnel exchange to address shortages and gaps in local industry and university capabilities.
- The need to establish a virtual 'Australian Commercialisation Institute' to provide wrap around support to researchers and spinouts from leaders in the field.
- Completing a comprehensive scoping study on an Australian 'PoC' fund.[1]

1. AusBiotech. (2021). 'Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry'. Available at: https://www.ausbiotech.org/documents/item/680

SECTION 1:
RECOMMENDATIONS

RECOMMENDATIONS

RECOMMENDATION 1
PoC FUNDING

Creation of a national University PoC Scheme to support both clinical/technical PoC (additional clinical studies, prototype building and testing, validation, and maturation activities) and commercial PoC (regulatory and market access strategy, valuation approaches, management, and business planning) required to take basic research to a stage where it is mature enough to attract the interest of private capital.

- Approximately 80% of products tested at the PoC phase will be deemed commercially unviable.[2] Often opportunities are identified, but commercial development is abandoned due to the inability to find funding for the PoC and validation studies following the filing of the first provisional patent and the Patent Cooperation Treaty (PCT) patent.[3] Dr Chris Nave from Brandon Capital has noted that 'up to 96% of applications seeking funding from the Medical Research Commercialisation Future Fund are declined due to being too early in development or lacking key supporting data'.[4]
- This was a recurring point that was raised by multiple participants in our one-on-one interviews and was discussed at length at the roundtable. As such, several of our recommendations are related to addressing this fundamental issue.
- However, the question of who is responsible for conducting and funding this PoC was contentious. Most industry partners expressed a preference for university TTOs to have this responsibility, however it was also apparent that TTOs are currently not adequately resourced to do this at scale. Some TTOs may have a small amount of funding available for this purpose but this is inconsistent and can be difficult to access.
- Recent announcements have sought to address this challenge, including the establishment of Australia's first national biotech incubator to be funded with $40 million from the Medical Research Future Fund (MRFF) and operated by Brandon Capital via the MCRF which is structured to 'bridge the gap between where research grant funding finishes but before a technology is at a stage that it can attract its first seed investment'.[5]
- Similarly, the November 2021 announcement of the ***Trailblazer Universities Program*** includes a $30 million investment for successful universities to access Commonwealth Scientific and Industrial Research Organisation's (CSIRO) specialist equipment, such as a Test Lab, to improve the technology readiness level (TRL) and scaling of research to a point where private sector investment is more attractive.[6]

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2. Seyhan, A.A. (2019). 'Lost in translation: the valley of death across preclinical and clinical divide – identification of problems and overcoming obstacles', Translation Medicine Communications, 4(18).

3. Association of Australian Medical Research Institutes. (2014). 'Enhancing the Commercialisation of Outcomes of Health and Medical Research'. Available at: https://aamri.org.au/wp-content/uploads/2014/05/aamri_submission_enhancing_commercialisation.pdf

4. MCRF. (2021). 'Australia's first national biotech incubator established with $40m MRFF investment'. Media release. Available at https://www.mrcf.com.au/

5. Ibid.

6. Australian Government. (2021). Trailblazer Universities Program, Program Guidelines, Department of Education, Skills and Employment.

- There are also several international examples of successful Government and industry co-funded programs that address this gap. For example, the ***NZ Pre-Seed Accelerator Fund*** (established in 2004) and the ***Proof of Concept Programme of the European Research Council*** (established in 2011).
- At the University of Cambridge, the collaborative venture 'Apollo Therapeutics' provides translational funding and drug discovery expertise for therapeutics. The venture is established between three global pharmaceutical companies (AstraZeneca, GlaxoSmithKline, and Johnson & Johnson) and the TTOs at Imperial College London, University College London, and University of Cambridge (discussed in further detail in the Imperial Innovations case study).
- We recognise that there are a range of existing programs that are already aimed at addressing this challenge, including the ***MTPConnect Biomedical Translation Bridge Program***, the NSW Health Commercialisation Training Program (which was developed in conjunction with Cicada Innovations) and the ***ANDHealth+ Program***, however we believe a unique dedicated model which tests both clinical and commercial PoC models can help test and progress promising research as well as encouraging a 'fail fast' approach for technologies which may not have commercial validity.

RECOMMENDATION 2
INCENTIVISE

Adjust standard Enterprise Bargaining Agreements (EBAs) and Key Performance Indicators (KPIs) for academic researchers who are seeking to explore the commercialisation potential of their research. This would allow the researcher to consider the global commercialisation landscape for their research and to better understand the industry landscape, private capital interest and competitor profile (amongst other things). This could be accompanied by dedicated programs for these researchers to enable them to experience and understand commercialisation opportunities. The PoC Scheme described above and the ACI outlined below could also be resources that these researchers could engage with to gain these insights.

- Another recurring theme was that Australian academic culture does not sufficiently value or understand the process of commercialisation. Publication remains the KPI for current academic investigators in the Australian peer-reviewed competitive grant system.[7]
- It is therefore important to incorporate within the grant funding system metrics which enables a comparison of one scientist's publication success with another's commercial efforts.

7. AAMRI. (2014).

- To resolve this, we propose the introduction of an 'industry-track' for academic researchers which would allow for an adjustment to the standard composition of an academic schedule (40:40:20 comprising teaching/research/service) to allow exploration of commercialisation and entrepreneurship opportunities. For example, the explicit reduction in publication requirements could enable a carve out to understand commercial applications via industry partnerships or secondments. Additional KPIs specific to commercial outcomes (for example, industry co-investment in research; the filing of a joint industry-university patent; entering into a licensing arrangement) could also be built into the industry-track. This change could then be reflected in EBAs to formalise an alternative to the 'publish or perish' dynamic.
- Interestingly, this dovetails with the Government's recent announcement of the ***Trailblazer Universities Program*** which states that in order to be eligible universities must have: 'industrial arrangements that promote a high-performance culture and support the achievement of commercial outcomes, such as through a clearly articulated remuneration, reward and promotional arrangements for academic researchers engaging in commercialisation activities'.[8]
- We also note there are already examples of alternative approaches to address this same cultural challenge in place at other research institutions. For example, the Institute for Molecular Bioscience (IMB) at The University of Queensland runs a mandatory commercialisation boot camp for all PhD students, and the Walter and Eliza Hall Institute (WEHI) runs a Business Development Intern Program for early career researchers. However, it has been noted that these programs are 'under-resourced and uncommon and many are still in a pilot stage'. To achieve scale, a Government backed national rollout similar to programs in Denmark and France would be required.[9]

RECOMMENDATION 3
GLOBAL PLACEMENTS

Industry fellowships should consider global placements in order to access international R&D infrastructure and maximise the learning opportunity. Fellowships have to be meaningful and of significant duration, for example, a minimum 12-month period. This could include PhD students, but it is necessary to factor in a minimum training period before they begin adding value to the project.

- This will complement existing programs which are designed to deliver systemic improvement in Australia's medical technology, biotechnology and pharmaceutical workforce by providing industry experiences and skills, including ***Researcher Exchange and Development within Industry (REDI)*** initiative, the ***Australian Research Council Linkage Program*** and the Knowledge Commercialisation Australia scholarship.
- We note The University of Sydney's recent support for the review of the R&D Tax Incentive's recommended introduction of 20% collaboration premium for the non-fundable tax offset. This could potentially defray or cover the cost of employing new PhD or equivalent graduates for their first three years.[10]

8. *Australian Government. (2021).*
9. *Mondschein, J., Roy, R. and Naidoo, V. (2021). 'Our unis are far behind the world's best at commercialising research. Here are 3 ways to catch up'. The Conversation, 4 May 2021. Available at https://theconversation.com/our-unis-are-far-behind-the-worlds-best-at-commercialising-research-here-are-3-ways-to-catch-up-159915.*
10. *The University of Sydney. (2021). University Research Commercialisation Consultation Paper. Available at https://www.sydney.edu.au/about-us/governance-and-structure/university-policies.html#policy-submissions*

RECOMMENDATION 4
UPSKILL

Improved training and professional development opportunities for commercialisation offices within Australian universities.

- For example, increased uptake of Registered Technology Transfer Professionals (RTTP) accreditation. RTTP was developed by the Alliance of Technology Transfer Professionals (ATTP) as a globally recognised professional designation. The RTTP framework recognises demonstrated competence and experience across the breadth of technology transfer, from IP commercialisation through to university business collaboration and start-up company creation.
- Increased recognition of existing Australian-specific courses, for example the 2-day ***Best Practices in IP Commercialisation*** course offered by Knowledge Commercialisation Australia.
- AusBiotech could consider redesigning a tech transfer summit as a dedicated forum for best practice sharing and emerging trends.
- Universities could also organise and host networking events that bring together research academics, tech transfer staff, and relevant industry partners. These events could include a portion with presentations, pitches, or sessions from academics to present their research and would provide a potential opportunity for industry partners to be informed of relevant commercial opportunities.
- Supporting TTO staff attendance at global conferences, including the annual ***Biotechnology Innovation Organisation (BIO) Convention***, which is the world's largest biotech partnering event.

RECOMMENDATION 5
COMMERCIALISATION INSTITUTE

Partner with AusBiotech on the development of an Australian Commercialisation Institute[11] to leverage expertise, by forming strategic partnerships to access more sophisticated insights and assess the commercial potential of university research.

- As highlighted in Recommendation 1, an often-neglected aspect of health and medical research patent filing is the absence of a comprehensive commercial business case that supports engagement with industry and private capital.
- This is the fundamental idea underpinning the ACI and the proposal for MBA-FMH Seed Fund (outlined below).
- There are a multitude of ways that the ACI could provide support to academics seeking to understand the commercial application of their work. These are discussed in further detail below.

11. We recognise that an Australian Institute for Commercialisation does already exist (http://www.ausicom.com/), however we believe the ACI will be unique in its design and will have a specific focus on the technology transfer and industry engagement of health and medical research (biotech) discoveries.

RECOMMENDATION 6
SECONDMENTS INTO INDUSTRY

Secondments for TTO staff within private equity/venture capital firms to understand their approach to valuing pre-clinical invention disclosures/IP. This is an extension of current programs focused on researchers.

- These programs would be designed in collaboration with private firms to provide TTO personnel with a deeper understanding of how private capital assesses pre-clinical research and the steps involved in de-risking the research to a point where investment can occur.
- In addition to best practice sharing, these programs could see the increased adoption by TTOs of the strategic resources that private equity/venture capital firms use to inform their due diligence, including access to international data sets, patent landscape analysis tools and a global panel of subject matter experts.

RECOMMENDATION 7
TRACK COMMERCIALISATION

Develop metrics to assist TTOs to track their commercialisation progress. This can be complemented by the development of standard term sheets outlining baseline terms and conditions to streamline the negotiation of licencing or other commercial arrangements.

- ***Knowledge Commercialisation Australia*** has established the SCOPR which enables TTOs to benchmark performance and could be used to establish performance metrics.
- Internationally, the Association of University Technology Managers (AUTM) provides benchmarking information enabling peer group comparison based on invention disclosures, new patent applications, licensees and options, gross licensing income and start-ups formed.[12]
- Individual Australian TTOs could also establish standard timeframes for each step in the negotiation of a licensing arrangement and for other commercial contracts.
- The ***Higher Education Research Commercialisation IP Framework*** consultation paper also discusses this issue and ultimately seeks to produce standardised agreements to incentivise and increase partnerships between industry and university.
- The UK Intellectual Property Office has developed the ***Lambert Toolkit*** which contains model agreement guidance for university and business collaboration, however it has been noted that only a small percentage of deals utilised these unmodified templates as industry partners continue to expect to include their own agreement terms.[13] We believe this issue can be mitigated by strategies to reduce the asymmetry between parties when negotiating commercial terms as outlined in Recommendation 8.

12. AUTM. (2020). 'AUTM 2020 Licensing Activity Survey'. Available at https://autm.net/AUTM/media/SurveyReportsPDF/FY20-US-Licensing-Survey-FNL.pdf. See also, the Statistics Access for Technology Transfer Database (STATT) tool operated by AUTM.
13. Intellectual Property Office. (2013). 'Collaborative research between business and universities: The Lambert Toolkit 8 years on'.

RECOMMENDATION 8
INTEGRATE BUSINESS KNOW HOW

Additional clarity on the commercialisation potential of preclinical IP via the development of a collaborative national program between business students and academic researchers. A proposed model for how this program could operate at The University of Sydney is described below via the curriculum for the MBA-FMH Seed Fund and the completion of The University of Sydney Commercialisation Template.

- The absence of dedicated commercialisation training for academic researchers has been identified as a barrier to entrepreneurship and translation. A range of useful programs have been developed to bridge this divide, including: ***MTPConnect Biomedical Translation Bridge Program***, the ***NSW Health Commercialisation Training Program*** (which was developed in conjunction with Cicada Innovations); and the ***ANDHealth+ Program***.
- We believe that these resources provide a critical foundation on the key concepts and the curriculum for MBA-FMH program would be designed to complement these resources by requiring teams to apply the principles to a real-life project.
- A priority of the MBA-FMH program would be the in-depth analysis of the theoretical valuation of pre-clinical projects to ensure a thorough consideration of the commercial landscape that the project is targeting.
- The valuation of pre-clinical IP relies on a number of assumptions that are difficult to determine with precision and which will inevitably be subjective in nature. Nevertheless, the process of building a valuation model will require the MBA-FMH team to compile available data and interrogate the commercial landscape in a way that would not typically occur until a much later stage. In itself this will compel the team to test some of the pre-conceived views about the research and require the team to take steps to address potential weaknesses in the value proposition.

RECOMMENDATION 9
ATTRACT THE RIGHT TALENT

Access the global pipeline of TTO talent by creating opportunities commensurate with those in the US and UK. This may require re-evaluating the optimal personnel size and resourcing requirements for Australian TTOs. Establish an Australian association of university technology managers with an annual forum for sharing ideas, trends, and best practices.

- Government support could assist in providing additional resources through a third-stream funding program dedicated to developing a critical mass of expertise in knowledge transfer. For example, the third-stream funding available in the UK's ***Higher Education Innovation Fund***.
- UniQuest provides an existing successful example of the benefits of a substantial and experienced commercialisation team with team members embedded in each partner institution to help identify commercialisation opportunities and to develop an entrepreneurial culture among researchers. This has contributed to a higher success rate of commercialisation of biomedical research than its counterparts in other institutions.
- There have also been calls for the creation of a national TTO that universities could access through a hub and spoke model which would allow for the concentration of resources and expertise and could provide a breadth of support to academic researchers that is not possible at an institutional level.

RECOMMENDATION 10
FREEDOM TO PUBLISH

Industry should ensure publication requirements can be accommodated as part of industry-funded research. Academic journal publication remains an important criterion for grant funding and career progression.

- Most industry partners appreciate that the publication of studies is central to the mission of scientific advancement as well as supporting the development and career progression of academics. Likewise, most academics appreciate the commercial realities that limit the sharing of certain proprietary information.
- However, an open dialogue between academics and industry partners can lead to mutually agreeable strategies to accommodate these competing requirements, leading to broader successful collaboration and a robust ecosystem.
- We recommend development of some tools and collateral to facilitate dialogue.

SECTION 2:
ANALYSIS AND CASE STUDIES

COMMERCIALISING AUSTRALIAN UNIVERSITY IP AND THE AUSTRALIAN BIOTECH SECTOR

Universities currently employ a number of strategies to support the sharing of opportunities with private investment. However, survey data shows Australian public research organisations made an average of about 20 invention disclosures in 2016, roughly the same as in 2004 despite the more than fourfold increase in research output. Australia's average rate of 20 invention disclosures compares to more than 40 in Canada, more than 60 in Israel, and over 120 in the US. Nevertheless, it has recently been noted that the Australian universities are positioned for a multibillion dollar 'explosion in translation commercialisation over the next decade. If we can get it right'.[16]

Securing patents enables technology transfer and future partnering, licencing and spinout opportunities. IP generation alone, however, does not guarantee successful translation of research. For example, although patent applications arising from stem cell research in Australia have had a high success rate (96% awarded), very few have developed into products entering clinical trials.[17]

The difficulties in conversion are also evidenced by Australia's inability to produce a single home-grown pharmaceutical giant (excluding CSL which originated as a government-owned pharmaceutical manufacturing business). The success rate of Australian biotech companies on the ASX has been mixed at best with a number of high-profile IPOs struggling to convert promising clinical data into commercialised products. This has led to the observation that 'since 2010, not a single VC-backed biotech has progressed to listing on the ASX.'[18] The focus of private capital has instead been on identifying high potential drug development programs to provide capital support before on-selling the program to a global player.

For example, the leukaemia drug Venetoclax, which is estimated to achieve annual sales of US$1.48 billion, originated as a research program at WEHI in the early 2000s with the discovery of a cancer survival protein called BCL-2.[19] In 2006, researchers at WEHI discovered a series of compounds that would block BCL-2 and filed a patent, which was licensed to the US pharmaceutical giants, Genentech and Abbvie, with WEHI maintaining a claim on future royalties. This led to royalty rights in the range of US$325 million.[20]

There is no doubt that this was an outstanding commercial outcome for WEHI, however it leaves open the question of whether Australia will be able to build a more mature, self-sustaining ecosystem while large portions of the value chain occur in overseas markets. For now, this may represent a second order challenge, as given Australia's current commercialisation output, we must first consider strategies to increase the filing of patents that can convert to breakthrough treatments for patients. This is the focus of the next section of our paper.

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14. For example, The University of Sydney maintains a list of licensable intellectual property, see https://www.sydney.edu.au/engage/industry-business-partnerships/license-our-intellectual-property.html

15. Tudge, A. (2021). 'Lifting the impact of universities to strengthen Australia's future', Speech, 26 February 2021.

16. Hare, J. (2021). 'Get ready for research commercialisation explosion: IP Group', AFR, 17 October 2021.

17. Patent Analytics Hub. (2019). Patent Analytics on Stem Cell Technologies Underlying Regenerative Medicine 2019. Available from: https://www.ipaustralia.gov.au/tools-resources/publications-reports/patent-analytics-stem-cell-technologies-underlying-regenerative

18. Molloy, P. (2021). 'Australian Biotechnology: Promissory Expectations and Ecosystem Performance far from the Global Superclusters'. Journal of Commercial Biotechnology, 26(1), 52-60.

19. Thomson Reuters. (2016). 'Drugs to Watch 2016: Market Insight Report', February 2016.

20. Molloy, P. (2021).

CONSIDERATIONS WHEN COMMERCIALISING PRE-CLINICAL IP

Invention disclosures and patents

Invention disclosures are the first step in the patenting process. The invention disclosure should explain the importance of the invention, why it improves on current designs, and what differentiates and distinguishes the invention from other prior art. It also provides an opportunity for TTOs to assess whether there is any monetary value in the invention and what potential paths towards IP protections and commercialisation can occur. In 2020, there were 1,393 invention disclosures reported in the SCOPR.[21]

A patent is the legally enforceable right that is granted for any device, substance, method, or process that is new, inventive, and useful.[22] A standard Australian patent gives the owner exclusive rights to commercially exploit the invention for a period of up to 20 years. There are two major filing routes for patent applications: international via the Patent Cooperation Treaty (PCT) and national (National-Phase Entry).[23] In 2020, there were 427 new patent applications reported in the SCOPR.[24]

From a commercialisation perspective industry partners will want to know that any background IP of research collaborators or third parties has been defined and secured and that there is clear ownership allocation if several parties are involved.[25]

The University of Sydney IP Policy clarifies that, unless otherwise provided, the net development proceeds from IP owned by, or developed by, the University will be distributed as follows:

a. the first $250,000 to the originator(s); and then
b. one third to the originator(s);
c. one third to the relevant faculty or business unit;
d. one third to the Vice-Chancellor's Innovative Development Fund.[26]

An effective IP strategy must also include appropriate steps to gain competitor intelligence and to analyse and provide reassurance to potential investors that there is sufficient freedom to operate. The IP landscape for many diseases is likely to be crowded which will necessitate extensive searches of patent databases to identify any potentially relevant third-party IP.[27] Although this process will typically be completed by TTOs, this exercise could also form a component of the MBA-FMH Seed Fund program to reinforce to participants the critical importance of IP management as the foundation of any successful commercialisation process.

There is also growing evidence on the importance of early collaboration with industry when seeking to patent. This collaboration can enable industry to provide critical insights on the structure and filing of the patent to maximise its defensibility and value. The Australian Innovation System Monitor (October 2018 edition) found that across all Australian patents, just 2% involved collaboration (however the figure was

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21. Knowledge Commercialisation Australia. (2021). Survey of Commercialisation Outcomes from Public Research. KCA. Available at https://techtransfer.org.au/wp-content/uploads/2021/10/SCOPR-REPORT-2020-1.pdf
22. Patents Act 1990 (Cth).
23. Australian Government. (2015). A patents analytic study on the Australian Pharmaceutical Industry. Department of Industry, Innovation and Science, September 2015.
24. KCA. (2021).
25. Feedback from stakeholder interviews.
26. The University of Sydney. (2016). Intellectual Property Policy 2016, 10 May 2016, clause 13.
27. Nonaka, H. (2018). 'Freedom to Operate in the Pharmaceutical Industry'. Nomos Verlagsgesellschaft. Available at: https://www.jstor.org/stable/j.ctv941tn6. See also, the role of the ACI in providing support via its strategic partnerships.

8.3% for biotechnology patents).[28] IP Australia has identified a positive relationship between collaboration and patent impact and that funding schemes which mandate collaboration with industry deliver a greater return in terms of patent applications.[29]

Challenges with translation and achieving PoC

There is a consensus both in academia and industry that more support is required to translate preclinical science to human applications which is exacerbated by the fact that many research findings are either irreproducible or false.[30]

Many published research findings in biomedical research may not be reproducible for a myriad of reasons. This could be due to methodological differences in additional clinical studies, or due to unexpected clinical and safety responses when moving from the cellular level to an animal study.[31] This has led to the claim that, in modern research, false findings may be the majority or even the vast majority of published research claims.[32] The low conversion rate has led to calls for basic science to consider strategies to better inform translational opportunities. For example, more predictive animal models, earlier toxicology evaluation, better biomarker identification and increased communication with regulators.

Systematic reviews: setting projects in the context of previous research

A strategy for reducing this risk is to increase the time and resources invested in undertaking a systematic review of existing research to situate a project within the existing framework of completed studies. Systematic reviews use predefined methods to identify, select, and critically appraise all available and relevant literature to answer a given question in an unbiased manner.[33] They prevent the unnecessary duplication of experiments and, critically, offer the means to support scientific and technological developments that replace, reduce, or refine the use of animals in research. A systematic review can identify knowledge gaps which will inform the clinical trial design to address the unmet need. Empirical evidence suggests that preclinical studies, in particular, lack methodological rigour and could benefit from a structured review of existing research.[34] There are existing generic online courses which can provide an introduction to systematic review methodology,[35] however a basic outline is below:

Step 1: Define the research question and the methods to be used for the search strategy.

Step 2: Review the literature for comparable studies/papers from established databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- PubMed
- Ovid
- Collaborative Approach to Meta Analysis and Review of Animal Data from Experimental Studies (CAMARADES) Systematic Review Facility which undertakes preclinical systematic review and meta-analysis to investigate translational failure.[36]

Step 3: Complete a meta-analysis to combine the outcome data of individual studies (this could require the selection of an outcome measure to compare across studies).

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28. IP Australia. (2018). 'Collaborative research grants lead to better IP outcomes', Australian Intellectual Property Report 2018 Accessed on 6 December at https://www.ipaustralia.gov.au/ip-report-2018/research-grants.

29. Ibid.

30. Ioannidis J.P. (2016). 'Why Most clinical research is not useful'. PLoS Med, 13(6).

31. Seyhan, A.A. (2019). 'Lost in translation: the valley of death across pre-clinical and clinical divide – identification of problems and overcoming obstacles'. Translational Medicine Communications, 4(18).

32. Ioannidis J. (2005). 'Why Most Published Research Findings Are False'. PLoS Med, 2(8): e124.

33. Soliman, N., Rice, A., & Vollert, J. (2020). A practical guide to preclinical systematic review and meta-analysis. Pain, 161(9), 1949–1954.

34. Sena E.S., Currie G.L., McCann S.K., et al. (2014). 'Systematic reviews and meta-analysis of preclinical studies: why perform them and how to appraise them critically'. J Cereb Blood Flow Metab, 34: 737–42.

35. Soliman, N., Rice, A., & Vollert, J. (2020). A practical guide to preclinical systematic review and meta-analysis. Pain, 161(9), 1949–1954. https://doi.org/10.1097/j.pain.0000000000001974.

36. CAMARADES. (2021). Systematic Review Facility. Available at https://syrf.org.uk/mission.

In practice, the completion of a comprehensive systematic review is resource intensive and requires a level of expert involvement which is beyond the scope of the MBA-FMH team. For example, in 2013, a systematic review of animal models of multiple sclerosis identified over 9,000 potentially relevant studies from the systematic search. By 2016, a project to systematically curate the evidence from animal models of depression had identified over 70,000 potentially relevant studies.[37] Therefore, the need for additional tools and resources to assist with the collation of existing research into systematic reviews and meta-analyses will be critical. This is also a space where artificial intelligence (AI) is likely to have an increasingly important role due to its efficiency as a data mining tool.[38]

Role of AI in supporting drug discovery and PoC

The probability that a small molecule successfully completes clinical trials has remained constant for 50 years despite improvements in screening methods which have improved the efficiency of the research process, with more leads being tested against more targets and better understanding of mechanisms of action and ADMET principles (absorption, distribution, metabolism, excretion and toxicity).[39]

This has been in part due to the absence of reliable non-animal/human models for assessing the efficacy of compounds prior to initiating clinical development.[40] In addition, traditional methods of identifying genes in vitro, followed by generating experimental animal models of human disease in vivo, has been a challenging process because the targets and drugs developed in animals have often failed in human studies with a success rate of translation from animal models to clinical cancer trials of less than 8%.[41]

Emerging AI tools can be used to refute or validate assumptions before animal or human trials are commenced by using computational techniques to project the impact of compounds based on a range of inputs. An example of AI in practice is the algorithm known as DeepTox which can identify features within the chemical descriptors of molecules to efficiently predict the toxicity of a molecule based on 2,500 predefined toxicophore features.[42] Other AI applications include predicting the structure of the target protein to design the drug molecule and predicting the drug-protein interactions to prevent polypharmacology.[43]

Google's AI network, DeepMind, is also achieving consistent success in its ability to determine a protein structure from its amino-acid sequence more quickly and efficiently than current lab-based methods. This could help to understand the function of thousands of unsolved proteins in the human genome which could eventually lead to a more complete understanding of gene variations which cause disease.[44]

The potential role of AI in supporting PoC in preclinical research is likely to evolve rapidly. In 2020, AI in cancer, molecular, and drug discovery received the most private investment in the field, attracting over $13.8 billion, more than quadruple 2019's total.[45] The role of systematic reviews (including the use of emerging AI tools) will require additional thought so that the curriculum is aligned with the time and resources teams have available.

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37. Bannach-Brown A, Hair K, Bahor Z, et al. (2021). Technological advances in preclinical meta-research. BMJ Open Science, 5:e100131. doi: 10.1136/bmjos-2020-100131.

38. Fleming, N. (2018). 'How artificial intelligence is changing drug discovery'. Nature. Available at: https://www.nature.com/articles/d41586-018-05267-x.

39. DiMasi, J. A., Feldman, L., Seckler, A. & Wilson, A. (2010). Trends in risks associated with new drug development: success rates for investigational drugs. Clin. Pharmacol. Ther. 87, 272–277.

40. Johnson, R. and Zhou, S. (2019). 'Pharmaceutical Probability of Success'. Alacrita Consulting. Available at: https://cdn2.hubspot.net/hubfs/3828687/Alacrita_April2019/PDF/Pharmaceutical-Probability-of-Success.pdf

41. Isabella, W.Y., Evanview, N. and Ghert, M. (2014). 'Lost in translation: animal models and clinical trials in cancer treatment.' Am J Transl Research, 6(2): 114-118.

42. Mayr, A. (2016). 'DeepTox: toxicity prediction using deep learning'. Frontiers Environ. Sci, 3, 80.

43. Paul, D., Sanap, G., Shenoy, S., Kalyane, D., Kalia, K., & Tekade, R. K. (2021). 'Artificial intelligence in drug discovery and development'. Drug discovery today, 26(1), 80–93.

44. Callaway, E. (2020). 'DeepMind's AI makes gigantic leap in solving protein structures'. Nature 588, 203-204.

45. Stanford University, Artificial Intelligence Index Report. (2021). 'Measuring Trends in AI'. Available at: https://aiindex.stanford.edu/report/.

Overview of valuation

The valuation process for pre-clinical IP is notoriously difficult. As with other pre-revenue companies, valuing a biotechnology project cannot be achieved using standard valuation multiples like EBITDA or P/E. In addition, due to the inherent physical and clinical differences between technologies, designing an objective valuation methodology is challenging. To the extent that objective valuation methods do exist they remain dependent on a range of subjective inputs to generate estimates of value.

Each research project or patent will represent a unique value proposition based on multiple variables, with many being difficult to validate using objective metrics. For example, the value proposition of any given project will depend on: the total available market for the final therapeutic product, the anticipated clinical qualities of the drug, the extent of existing competition, development costs and timelines and, most importantly, the phase-specific probabilities of success.[46] Even if an accurate projection of future sales could be determined, the true value of the IP may vary for other reasons related to the resources, specialisation and existing portfolio of a potential investor.

To manage this uncertainty, industry analysts employ a number of strategies to model future revenues while discounting for the inherent risk. We discuss the most common strategy, risk-adjusted net present value (rNPV), below.

As valuation in pre-clinical projects is ultimately about risk management, investors can employ a number of other options to help share and manage risk, including upfront fees, milestone payments and royalties.

UPFRONT FEE	Recipient entitled to cash (or equivalent payment).
MILESTONES	Recipient entitled to defined payments linked to performance events.
ROYALTY	Recipient entitled to percentage of sales or profits.

Upfront fees can be provided where it is necessary to recover costs for past research and the cost of applying for and maintaining IP rights.

Milestone payments are based on performance and provide a means of bridging the valuation expectations gap between a licensee and licensor. Performance milestones are those that can be satisfied with a reasonably predictable level of commercial diligence. Common milestones include first commercial shipment or sale of the licensed product, regulatory agency approval, closing of a financing transaction raising a specified amount of funds, and achieving specified sales targets during a defined period or by a certain date.[47] The trigger event for milestone payments should be as clearly defined as possible to avoid disputes.

Royalties can be calculated as a percentage of sales or on a per-unit basis.[48] Percentage of net sales is most common and allows the royalty amount to automatically increase with increases in price. The

46. Stanford University, Artificial Intelligence Index Report. (2021). 'Measuring Trends in AI'. Available at: https://aiindex.stanford.edu/report/

47. Lee, J.H., Kim, E., Sung, T. and Kwangsoo, S. (2018). 'Factors affecting pricing in patent licensing contracts in the biopharmaceutical industry'. Sustainability, 3 September 2018.

48. In this paper, the term 'royalties' should be taken to mean 'running royalties', which are defined as royalties earned on and tied to the sale of products.

average royalty rate will vary by treatment and clinical development phase. An analysis of average royalty rates in pharmaceuticals over a 5-year period from 2012 to 2017 found that, on average, a deal for a product at a pre-clinical phase would attract a rate of 8%, while Phase I trials would attract a royalty rate of 10% which increases to 14.5% for products in Phase III trials.[49] According to AUTM surveys, running royalties comprise as much as 70% of total licensing income for TTOs.

Methods for valuing pre-clinical IP to support industry engagement

As discussed above, the most commonly used approach is the risk-adjusted net present value (rNPV) method. This methodology provides a framework for investors to consider the value of pre-clinical IP and a reference point for negotiations around licensing and royalty arrangements. The below section provides an explanation of the inputs in this model and highlights its limitations.

Using the rNPV model to value pre-clinical IP

The first step in a rNPV is to determine the NPV or discounted cash flow (DCF). The NPV can be calculated by subtracting the cost of developing the product from the expected revenue that the product will generate over its lifetime (which will generally correspond with its period of patent exclusivity).

The theoretical costs will initially include operating costs associated with the clinical development as well as manufacturing and production costs if the product achieves commercialisation. The theoretical revenue will be the sales of the commercialised product.

By deducting annual costs from annual revenue for the life of the project you can determine the available cash flow. This amount will then need to be discounted by the rate of return that could be achieved if that same amount was invested elsewhere over the same time period. This determines the present value of the future cash flow and represents the net present value of the pre-clinical IP.[50]

However, this calculation assumes a 100% chance that the product will achieve commercialisation which does not reflect reality in the clinical development of biotechnology. A comprehensive study of clinical drug development success rates has identified a less than 10% chance of products in Phase I trials of achieving Food and Drug Administration (FDA) approval. For this reason, it is necessary to utilise a risk-adjusted net present value to apply a development attrition rate as a discount factor to reflect the risk for each step of the clinical and regulatory approval pathway. Attrition rates can be estimated using historical information on the success rate in each development phase for products of a similar category (for example, type of disease) and can also be segmented depending on whether the candidates are New Molecular Entities (NMEs), non-NMEs, biologics or vaccines.[51]

Despite the availability of comprehensive studies, there is no hard or fast rule as to the application of discount rates for clinical development milestones, but it is generally accepted that the more mature the research, the lower the discount rate (50%+ for pre-clinical, which can reduce as a product proceeds through clinical trial phases).[52] In some cases pre-clinical IP may be subject to further discounting to adjust for risk associated with the pre-clinical data quality and integrity. This can even see the valuation of a project attract a negative risk adjusted net present value which may not align with the expectations of the research team that developed the technology.[53]

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49. Munter, S. (2021). 'Maximising Royalty Rates Opportunities in Pharma Licensing: Analysis of Average Royalty Rates in Pharma by Phase and Therapy Area'. Medtrack®.

50. Bratic, W., Blok, J.R., Gostola, M.M. (2014). 'Valuation of early-stage companies in the biotechnology industry'. Journal of Commercial Biotechnology, 20, 51-58.

51. Hay, M., Thomas, D., Craighead, J. et al. (2014). Clinical development success rates for investigational drugs. Nat Biotechnol, 32, 40–51.

52. Woo, J., Kim, E. Sung, T.E., Lee, J., Shin, K. and Lee, J. (2019). 'Developing an Improved Risk-Adjusted Net Present Value Technology Valuation Model for the Pharmaceutical Industry'. Journal of Open Innovation, 22 July 2019.

53. Hait, W.N. and Stoffels, P. (2021). 'A primer for academic entrepreneurs on academic-industrial partnerships'. Nature Communications, 12, Article number: 5778.

CASE STUDY:
APPLICATION OF RNPV TO A THEORETICAL BIOTECH

Overview: The below calculation is based on the expected revenue for a theoretical pre-clinical patent if it was to achieve commercialisation:

- **Patient population:** 1 million
- **Estimated market share:** 10%
- **Estimated market size:** 100,000 patients
- **Market price:** $200,000
- **Total available annual revenue:** $2 billion
- **This then needs to be risk-adjusted for each phase of clinical development.**

CLINICAL STAGE	MARKET
Pre-clinical	20%
Phase I	30%
Phase II	40%
Phase III	70%
Regulatory approval	90%
Market	100%

Therefore, for a product in the pre-clinical phase there is a 20% chance of achieving commercialisation which would require any expected future revenue to be weighted accordingly.[54] This means that the potential maximum $2 billion in sales would correspond with a figure of $400 million at the pre-clinical phase which would then be adjusted following the completion of subsequent milestones.

The rNPV valuation will change as each clinical development phase is completed:

- **Phase I:** $600m
- **Phase II:** $800m
- **Phase III:** $1.4b

Other considerations to strengthen the integrity of the rNPV model:

- Monte Carlo simulation methodology can be utilised to simulate changes to these inputs based on a statistical probability distribution for each input (for example, the overall market size, pricing, competitor behaviour) to create an overall probability distribution on the outcomes of the rNPV model.
- Sensitivity analysis may also help inform how different inputs will affect the estimated value.

54. Friday.capital. (2021). 'Valuing life sciences companies using the rNPV methodology'. Available at https://www.friday.capital/insights.

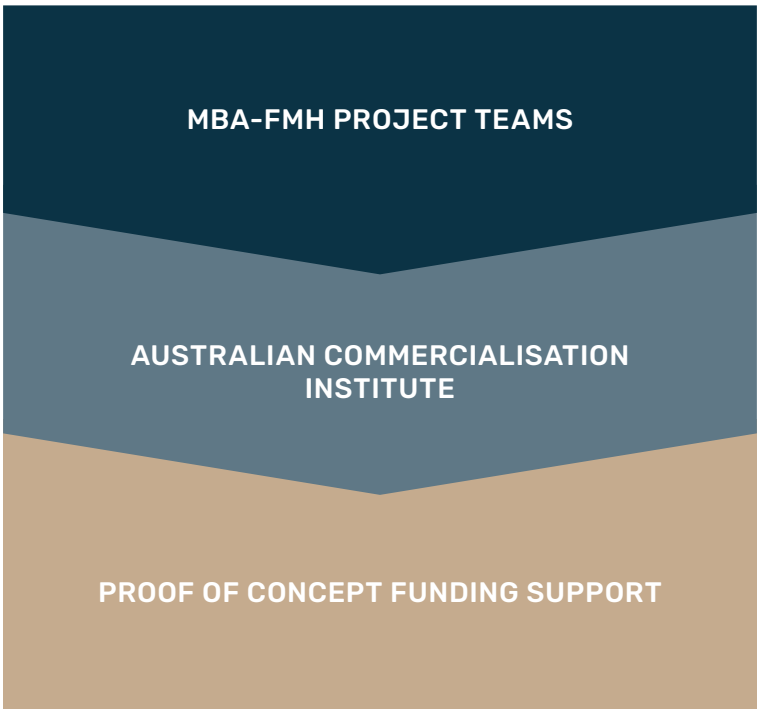
MBA-FMH SEED FUND, THE ACI AND PoC FUNDING SUPPORT

Both the ACI and the MBA-FMH Seed Fund are aimed at delivering a similar outcome – driving individual researchers, research teams and pre-clinical patent holders to interrogate the translation potential of their projects at an early stage to support a patenting and research strategy that maximises the likelihood of achieving a commercial outcome.

Conceptually, the MBA-FMH Seed Fund, the ACI and the PoC funding could represent a continuum of support for early-stage researchers (see Figure 2 below). The MBA-FMH Seed Fund would naturally be relevant at a slightly earlier stage on the commercialisation journey and will incorporate a structured curriculum to reflect that importance of providing a deep learning experience as well as offering the potential for real world translation opportunities.

The ACI's remit will likely be much broader reflecting the need for multiple entry points enabling access to all universities and research institutes in line with a national incubator model. The ACI could provide an important resource to rapidly provide researchers with commercial insights to inform the value proposition of their research.

FIGURE 2: *Continuum of Support for Early-stage Researchers*



MBA-FMH Seed Fund – Overview of program

The absence of dedicated commercialisation training for academic researchers has been identified as a barrier to entrepreneurship and translation. A range of useful programs have been developed to bridge this divide, including:

- *MTPConnect Biomedical Translation Bridge Program*
- *NSW Health Commercialisation Training Program* (which was developed in conjunction with Cicada Innovations); and the
- *ANDHealth+ Program*

We believe that these resources provide a critical foundation on the key concepts and the curriculum for MBA-FMH program would be designed to complement these resources by requiring teams to apply the principles to a real-life project. A priority of the MBA-FMH program would be the in-depth analysis of the theoretical valuation of pre-clinical projects to ensure a thorough consideration of the commercial landscape that the project is targeting.

As described above, the valuation of pre-clinical IP relies on a number of assumptions that are difficult to determine with precision and which will inevitably be subjective in nature. Nevertheless, the process of building a rNPV model will require the MBA-FMH team to compile available data and interrogate the commercial landscape in a way that would not typically occur until a much later stage. In itself this undertaking may compel the team to test some of the pre-conceived views about the research and require the team to take steps to address potential weaknesses in the value proposition.

For example, the team may find it difficult to locate data points that are supported by peer reviewed evidence (requiring additional sources and strategies to validate their assumptions when presenting the value proposition to industry partners). They may uncover existing patents that could narrow their freedom to operate (requiring the team to optimise their patenting and commercialisation strategy). And the list goes on.

Even a model which is reliant on a number of difficult-to-validate assumptions can serve a useful function as a base case for negotiations with industry partners as well as providing a framework for the research team to think about structuring milestone payments, equity sharing and royalty rates.[55]

For example, in order to build a credible rNPV model a deep dive will be required in the following areas:

- Clear explanation of the Target Product Profile (TPP) (see Figure 3 below).
- Detailed analysis of the patent landscape to test defensibility and freedom to operate.
- Patent life remaining post commercialisation (usually in the range of 8-10 years).
- Commercial pricing strategy of any existing products (particularly for critical overseas markets, including US, Europe, Japan and, increasingly, China). For markets that utilise health technology assessment methodology (for example, Australia, Korea, Taiwan) consideration will also need to be given on the collection of pharmacoeconomic models and data that would support claims of clinical superiority.
- Developing a message map to highlight essential points of difference compared to existing treatment options (e.g. clinically superior outcomes, improved safety profile, shorter treatment duration).
- Consideration of whether emerging AI-tools and/or AI-start-ups could accelerate the determination of clinical/technical PoC.

55. Stewart, J., Allison, P. & Johnson, R. (2001). 'Putting a price on biotechnology'. Nat Biotechnol, 19, 813–817.

FIGURE 3: *Completing the Target Product Profile*

SCOPING What is the unmet clinical need? What are the specific indications? What is the total target population?	• Is the product indicated for treating an underlying physiological cause of a disease or reducing the symptoms of a disease? • Will the drug only be used for certain situations (i.e. relapsed or refractory)? • Are any separate tests required to determine suitability (i.e. genetic biomarkers)?
TECHNICAL Clinical pharmacology Route of administration Formulation and presentation	• Concise statement of the clinical pharmacology and actions of the drug in humans, including the biochemical or physiological mechanism of action • (If available) Summarise established mechanisms of action in animals or humans at various levels (i.e. receptor membrane, tissue, organ, whole body) • (If available) Results of available pharmacokinetic studies for drugs in the same pharmacologically active and chemically related class • Dose range considered to be safe and effective • Dosage adjustments required for certain patient types (i.e. paediatrics)
EVIDENCE Anticipated safety profile Expected clinical efficacy vs comparators	• Anticipated or acceptable levels of adverse events • Information about planned studies outlining how research team would develop evidence to support safety or efficacy benefits of primary or secondary endpoints in the selected population • Proposed endpoints in trial design to demonstrate clinical efficacy vs comparators • This will require consideration of a clinical trial structure to demonstrate outcomes based on attainment of a p-value (see paragraph below)

Demonstrating clinical superiority in a clinical trial using the p-value

The p value is a statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing 2 treatments found that 1 seems to be more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 there is less than a 5% probability that the results occurred by chance, and it is considered that there is likely to be a significant difference between treatments. If the p value is 0.001 there is a less than 0.1% probability that the results occurred by chance and the results are considered highly significant. However, a statistically significant difference does not necessarily mean that the difference will be considered clinically significant.

Benefits of cross-faculty collaboration

As with existing international programs like the Oxford Seed Fund and Nucleate (see case studies below) the involvement of MBA students is designed to both expand the network of academic researchers and increase the range of entrepreneurial skills that will be available to support the development of a compelling business case. The practice is already established at The University of Sydney via courses and units of study that foster collaboration between MBA students and scientific teams in the fields of nanoscience, robotics, and computing.[56]

These insights and skillsets could then culminate in the development of a presentation to the ACI. We are proposing the development of a The University of Sydney MBA-FMH Commercialisation Template to assist in the development of this presentation as it would include detailed prompts to assist the team in addressing all necessary aspects of an investor presentation. For example:

- Elevator pitch
- TPP
- Supporting data
- Intellectual property landscape
- Needs analysis
- Power matrix
- Total available market
- Current treatment landscape
- Pathway to commercialisation
- Background on team members

The role of the ACI could be to provide feedback and direction to the team based on their completed template and presentation. The membership of the ACI will incorporate senior industry and academic experts who can stress test the assumptions included in the valuation model and the commercialisation template.

The ACI would also have at its disposal a greater level of resources to provide more granular insights, which could include access to a range of industry resources and strategic partners that could provide:

- Insight on the venture capital funds and/or pharmaceutical companies that are likely to have an interest in the TPP.
- Valuation experts who specialise in development rNPV models for pre-clinical and early-stage biotech companies who can deliver targeted feedback to the work completed by the MBA-FMH team.
- IP experts who can support the identification of the portfolio of patents related to a particular technology to provide an indication of the freedom to operate.
- Access to patent search and analytics software and access to global life science VC directories.
- Machine learning algorithms for title and abstract citation screening to support systematic review and meta-analysis of existing pre-clinical research.[57]

The clustering of expertise and resources within the ACI would also address a key finding in our stakeholder interviews, namely that university commercialisation offices were not equipped with funding or resources when benchmarked to international standards.[58] In practice, this means that there are significant discrepancies within individual university TTOs with respect to resources, expertise, and specialised personnel.

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56. Patten, S. (2021). 'Why universities are bringing together MBA students and scientists', AFR, 11 November 2021.

57. Bannach-Brown A, Hair K, Bahor Z, et al. (2021). Technological advances in preclinical meta-research. BMJ Open Science, 5:e100131. doi: 10.1136/bmjos-2020-100131.

58. AUTM. (2007). 'Nine Points to Consider in Licensing University Technology'. Available at https://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf

The ACI could therefore operate as a supra university TTO with the ability to deliver a critical mass of expertise that could provide best-practice support for technology transfer as proposed in our recommendations above. In particular, this could allow Australia to compete with the UK and US for the global pipeline of TTO talent through the creation of a deal flow that is commensurate with international biotech hubs. The ACI could also take a leadership role in mentoring and supporting a community of Australian university technology managers via the establishment of an annual forum for sharing ideas and emerging trends as occurs in the US (via AUTM) and the UK (PraxisAuril).

CASE STUDY:
IMPERIAL INNOVATIONS

The TTO for Imperial College London, Imperial Innovations, provides a best practice case study of IP packaging and protection. Imperial Innovations was specifically designed to protect and exploit commercial IP assets for private capital partners and an in-house Industry Partnerships and Commercialisation (IPC) team with membership from across the University, including the business school. The IPC was tasked with generating compelling summaries of licensable IP and was also equipped with in-house expertise in the recruitment of management teams and the formation of new companies. The model has proven so profitable that it was successfully spun-out as a separate company and floated on the London Stock Exchange in 2006 and has expanded its operations to include IP from Cambridge, Oxford, and the University College London.[59] This model provides an international best practice model which could inform the development and operation of elements of the MBA-FMH Seed Fund and the ACI.

PoC funding support

As a final step, we envision that MBA-FMH teams can be selected by the ACI for PoC funding support to further progress their project. However, we recognise that this would require the identification of resources to establish a seed fund as has been established at Oxford University (see below).

As set out in Recommendation 1, PoC funding support can encompass a wide range of activities, with the aim of de-risking technology to a stage where it can attract the first investment of private capital. This includes both clinical/technical PoC (additional clinical studies, prototype building and testing, validation, and maturation activities) and commercial PoC (regulatory and market access strategy, valuation approaches, management, and business planning).

CASE STUDY:
INFLAZOME LTD

Inflazome Ltd was a biotech start-up spun out of the University of Queensland (UQ) in 2016 by UQ's technology transfer company, UniQuest. The company was established to develop a pipeline of oral NLRP3 inflammasome inhibitors which block signals from proteins that activate inflammatory responses (inflammasomes). If successfully commercialised, the inhibitors could ultimately treat a range of chronic inflammatory conditions, including Parkinson's disease.

Although one asset (inzomelid) has progressed to human trials, the remainder of the portfolio was at an earlier stage with pre-clinical studies being completed on animal models using PET/MR, PET/CT, and radiotracer production to test specific critical components of the innate immune system.

Nevertheless, Swiss pharmaceutical giant, Roche, made the decision to acquire Inflazome and its pipeline for an upfront cash payment of $617 million as well as a commitment to (undisclosed) milestone payments for the attainment of further clinical milestones.[60]

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59. Hine, D. and D'Cruz, M. (2015). 'How Australian biotech can build a stronger biotechnology industry'. The McKell Institute, p 58.

60. Inflazome. (2020). 'Inflazome announces acquisition by Roche'. Media release. Available online at https://inflazome.com/press-release-21-sep-2020.html.

THE FUTURE OF FUNDING FOR BIOMEDICAL RESEARCH

It is also important to consider the emerging trends (particularly in the United States) that could potentially reshape the way biomedical research is funded and commercialised.

Research communities that are primarily reliant on government-funded programs and infrastructure (for example the NIH (National Institutes of Health) in the US and NHMRC (National Health and Medical Research Council)/ARC (Australian Research Council) in Australia share similar concerns about the administrative burden that accompany these programs and the conservative approach to assessing and approving research ideas. Success rates in these programs are shown to favour investigators with a detailed publication record and deep experience in the field which creates an inherent risk-aversion in grant applications and disadvantages early-stage researchers with innovative but untested ideas.[61]

This has led to attempts to disrupt the existing model by leveraging the ethos (and personal fortunes) of Silicon Valley entrepreneurs. Funds like ***ARC*** and ***Arcadia Science*** are specifically designed to free research teams from the administrative burden and uncertainty of grant rounds by offering multi-year unrestrained funding which encourages a higher degree of risk-taking. For example, ARC has raised $US650 million to fund 10-15 core investigators under renewable eight-year terms to 'pursue curiosity-driven research in an unfettered fashion'.[62]

It could be argued that the MRFF's multi-year 'missions' are an initial attempt to provide a longer runway and greater freedom to researchers in the Australian setting, and improvements in Australia's biotech ecosystem may encourage similar initiatives from private investors.[63]

An even more ambitious concept is known as DeSci which seeks to democratise access to funding via the use of Decentralised Autonomous Organisations (DAOs). In essence, a DAO is a community owned collective which can raise and invest funds for clinical research. Emerging initiatives in this space include ***VitaDAO*** and ***Molecule.finance*** which allow individuals to purchase tokens by contributing funds or other work. These tokens then enable the holder to engage in decision making, with holders voting to grant funds in exchange for ownership in the resulting IP. Importantly, funds are primarily targeted at early-stage, pre-patent projects potentially representing a unique solution to the PoC funding challenge.

It remains to be seen whether these new models will be sustainable vehicles for supporting early-stage research however, at a minimum, the decentralised nature of emerging platforms allows Australian researchers to tap directly into a global research marketplace. For example, the Molecule.finance platform enables research teams from around the world to list their pre-clinical research projects for review by potential investors. Interested investors can discover and follow projects, engage with the research teams and ask further questions. When interest from potential investors reaches a certain maturity, the IP moves into a new licensing platform built on Web 3.0.

Although untested, the potential to develop 'a new creator economy for researchers that allows for the rapid funding, discovery, and development of therapeutics through globally connected patient collectives' is a compelling proposition.[64]

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61. Mast, J. (2022). 'Inside the multibillion-dollar, Silicon Valley-backed effort to reimagine how the world funds (and conducts) science'. Endpoint News. Available at: https://endpts.com/inside-the-multibillion-dollar-silicon-valley-backed-effort-to-reimagine-how-the-world-funds-and-conducts-science/

62. ARC Institute. (2021). 'How is ARC Different?'. Available at: https://arcinstitute.org/about

63. Australian Government. (2021). 'Research missions'. Available at: https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund/mrff-research-themes/research-missions

64. Molecule. (2021). 'A new era of drug development'. Available at: https://www.molecule.to/

BEST PRACTICE CASE STUDIES OF BIOTECH AND BUSINESS SCHOOL COLLABORATION

CASE STUDY 1:
THE OXFORD SEED FUND

The Oxford Seed Fund is a student-led fund which provides access to capital, diverse investors, and community to Oxford University's most promising start-ups. The investing team is comprised of MBA candidates who source and evaluate deals, in consultation with an advisory board.

The Fund provides a training ground for MBA students in the mechanics of seed and venture funding and provides critical early-stage funding for emerging technology.

How does it work?

The Fund invests up to £50,000 in Oxford-affiliated start-ups and provides them with the network and support they need to scale. The current membership is made up of 11 MBA candidates whose experience ranges in venture capital, investment strategy, management consultancy, financial services, and entrepreneurship.

Background

In 2006, businessman David Bonderman and Philip Green each donated half a million pounds to create the Saïd Business School Venture Fund. The story goes that at an event in the Nelson Mandela lecture hall in the Saïd Business School, David Bonderman said he'd put in half a million if someone else put in another half. Never one to miss a publicity opportunity, high-street retailer Philip Green sitting in the audience, put his hand up and said *"yeah I will"*; bluff called, the fund was formed. ***This fund was a student-led organization that acted as a training ground for MBA students to learn about the seed and venture funding; the fund made a number of investments into student-led start-ups.*** The fund is no longer active and, in 2012, was superseded by the Oxford Seed Fund, managed from the Saïd Business School by a team of MBA students. The fund can invest up to £50,000.[65]

CASE STUDY 2:
NUCLEATE

Nucleate is a student-run organisation founded at Harvard University that connects scientists with MBA students interested in launching a venture via a mutual-matching process and provides a crash course in how to commercialise academic projects.

Eligible projects are those that have not received any equity funding but have preliminary PoC data that has not yet been licensed but which has existing IP to protect the technology (or a clear path to file IP within the next year).

Participation in Nucleate requires consent from the relevant institution's tech transfer offices. Once accepted, teams can then access industry mentors, legal strategy, and clinical consulting experts. After launching at Harvard in 2018, Nucleate has now partnered with over 50 institutions.

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65. Tom Hockaday. (2020). 'University Technology Transfer, What It Is and How to Do It', John Hopkins University Press.

How does it work?

There are 5 phases in the Nucleate journey:

- **Phase 1:** Connecting Scientists and Business Students.

Over the course of several events, scientific researchers have an opportunity to interact with trainees who would strengthen an early-stage start-up; program participants identify a (non-binding) partner to work with during the program.

- **Phase 2:** Mentorship from experienced serial entrepreneurs and biotech executives.

Once the core team has formed the program identifies and matches the team with 2-3 mentors according to scientific area and expertise needed by the core team. Meetings then occur on a weekly basis to work through program deliverables and foreseeable company roadblocks.

- **Phase 3:** Teams engage in a 12-week curriculum structure to address the critical aspects of company formation.
- **Phase 4:** Networking with operators and venture capitalists.
- **Phase 5:** Feedback from world-class venture capital (VC) judges.

"There's a missing layer between academia and the biotech industry, and potential start-up founders are getting left behind. We're launching Nucleate to empower the next generation of biotech leaders. Nucleate supports academic founders from the beginning, so they no longer need to graduate prematurely or lose ownership just to give initial life to their ideas," said Michael Retchin, Executive Vice President for Strategy at Nucleate.[66]

66. See for example, https://www.statnews.com/2021/09/28/students-launch-entrepreneurship-program-to-bring-new-faces-to-biotech/ and https://endpts.com/george-church-his-students-and-top-vcs-go-nationwide-with-a-biotech-training-camp/

SECTION 3:
PROPOSALS

PROPOSAL 1:
THE UNIVERSITY OF SYDNEY MBA-FMH SEED FUND

Objective:

To develop a free and collaborative student-run organisation that facilitates PoC of promising pre-clinical intellectual property.

PHASE 1: Connecting scientists and business students

Through a series of events, academic researchers with a potentially patentable discovery meet and match with MBA students who can provide a complimentary skillset to form a core team to work together during the program.

PHASE 2: Completing a structured deep dive on the commercialisation potential of an idea/invention disclosure/patent

- Clear explanation of the TPP.
- Detailed analysis of the patent landscape to test defensibility and freedom to operate.
- Patent life remaining post commercialisation (usually in the range of 8-10 years).
- Commercial pricing strategy of any existing products (particularly for critical overseas markets, including US, Europe, Japan and, increasingly, China). For markets that utilise health technology assessment methodology (for example, Australia, Korea, Taiwan) consideration will also need to be given on the collection of pharmacoeconomic models and data that would support claims of clinical superiority.
- Developing a message map to highlight essential points of difference compared to existing treatment options (e.g. clinically superior outcomes, improved safety profile, shorter treatment duration).
- Consideration of whether emerging AI-tools and/or AI-start-ups could accelerate the determination of clinical/technical PoC.

PHASE 3: Convert this into a Pitch Deck using The University of Sydney Commercialisation Template, incorporating

- Elevator pitch
- TPP
- Supporting data
- Intellectual property
- Needs analysis
- Power matrix
- Total available market
- Current treatment landscape
- Pathway to commercialisation
- Background on team members

This will provide a more expansive consideration of the translation potential of pre-clinical IP when compared with existing patent ***summaries*** and provide potential collaborators with a more comprehensive analysis of the commercial strengths.

PHASE 4: Mentorship from Australian Commercialisation Institute (incorporating Australia's most experienced academic entrepreneurs and biotech executives)

The Pitch Deck is presented by the core team to the ACI for guidance and direction to strengthen the clinical and business thesis. The core team is then matched with a mentor(s) according to scientific area and expertise needed. Meetings then occur on a weekly basis to work through program deliverables and foreseeable company roadblocks. There could also be opportunity for collaboration with existing programs from Cicada Innovations/NSW Commercialisation Training Program.

PHASE 5: Eligible to apply to The University of Sydney Seed Fund to support PoC

PROPOSAL 2:
A PROPOSAL TO CREATE AN 'INDUSTRY-TRACK' FOR ACADEMICS TO EXPLORE COMMERCIAL APPLICATIONS OF THEIR RESEARCH

Objective:

Australian academic culture does not sufficiently value, or understand the value of, commercialisation. To resolve this, we propose the introduction of an industry-track for academic researchers to formalise an alternative to the publish or perish dynamic.

Proposal:

The industry track would see an amendment to employment requirements for certain academics to allow exploration of commercialisation and entrepreneurship opportunities. This could include a change to the standard composition of an academic employment contract (40:40:20 comprising teaching/ research/ other). For example, a reduction in publication or teaching requirements for a period could enable a carve out of time to engage with industry partners, VCs, (or via an engagement with Australian Commercialisation Institute – see ***AusBiotech's Biotechnology Blueprint***) to understand the commercial applications of their research, without jeopardising career progression or academic promotion.

Additional KPIs specific to commercial outcomes could also be built into the industry-track (for e.g., industry co-investment in research; the filing of a joint industry-university patent; entering into a licensing arrangement), with input from industry to determine a clear set of KPIs that would allow comparison of commercial activities against more traditional academic publication outcomes.

Alternative approaches:

We note there are already examples of alternative approaches to address this same cultural challenge in place at other research institutions. For example, the Institute for Molecular Bioscience (IMB) at The University of Queensland runs a mandatory commercialisation boot camp for all PhD students, and the WEHI runs a Business Development Intern Program for early career researchers. Internationally, there are also Government-supported industry PhD programs where the Government funds a monthly wage subsidy for the company and covers the university supervision expenses. (See for example, the ***Denmark Industrial PhD program***.)

A CALL TO ACTION

Opportunities to improve the quality of life for people around the world are available right here within our grasp. This report provides ten achievable recommendations that have been stress tested through an extensive consultation process with industry.

With the marriage of expert researchers and prominent industry players, new discoveries can be accessible faster and brought to market earlier. Our evolving ecosystem is already contributing billions of dollars to the national economy, helping create new industries, and building the workforce that drives it.

Some of the recommendations are actionable in the short term, while some may require a longer-term approach. We invite you to submit your ideas to complement work already done and collaborate with us.

Join us on this journey...
Email: fmh.stratent@sydney.edu.au

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ACRONYMS

Acronym	Definition
ACI	Australian Commercialisation Institute
AI	Artificial Intelligence
AIS	Australian Institute of Sport
ARC	Australian Research Council
ATTP	Alliance of Technology Transfer Professionals
AUTM	Association of University Technology Managers
BIO	Biotechnology Innovation Organisation
DAO	Decentralised Autonomous Organisation
DCF	Discounted Cash Flow
EBA	Enterprise Bargaining Agreement
FDA	Food and Drug Administration
FMH	Faculty of Medicine and Health
IP	Intellectual Property
IPC	Industry Partnerships and Commercialisation
KPI	Key Performance Indicator
MBA	Master of Business Administration
MCRF	Medical Research Commercialisation Fund
MRFF	Medical Research Future Fund
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
NME	New Molecular Entity
PCT	Patent Cooperation Treaty
PoC	Proof of Concept
R&D	Research & Development
REDI	Researcher Exchange and Development within Industry
rNPV	Risk-adjusted net present value
RTTP	Registered Technology Transfer Professionals
SCOPR	Survey of Commercial Outcomes from Public Research
TPP	Target Product Profile
TRL	Technology Readiness Level
TTO	Technology Transfer Office
VC	Venture Capital
WEHI	Walter and Eliza Hall Institute of Medical Research

ACKNOWLEDGEMENTS

Special thanks to the following people for their support and contribution to this initiative:

- Professor Robyn Ward AM, Executive Dean and Pro Vice-Chancellor Medicine and Health, Faculty of Medicine and Health, The University of Sydney
- Michelle Burke, Director (2012-2021), Chair (2020-2021), AusBiotech
- Professor Guy Ford, Director, MBA Program, The University of Sydney Business School
- Holly Pobjie, MBA Candidate, The University of Sydney Business School
- Alex Best, MBA Candidate, The University of Sydney Business School
- Dr. Dean Moss, Chief Executive Officer, UniQuest
- Lorraine Chiroiu, Chief Executive Officer, AusBiotech Ltd
- Janine Richards, Director, Faculty Strategy and Partnerships, Faculty of Medicine and Health, The University of Sydney
- Nicholas McKay, Manager, Research Enterprise, Faculty of Medicine and Health, The University of Sydney
- Thalia Hambides, Research Support, Research Enterprise, Faculty of Medicine and Health, The University of Sydney

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Your feedback and collaboration is welcome as we strive for a national approach across the global stage.

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