

# Submission to Boosting the commercial returns from research discussion paper

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Submission by:  
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## **About the Murdoch Childrens Research Institute**

The Murdoch Childrens Research Institute (MCRI) has more than 1500 staff working across a broad research portfolio spanning population/public health and laboratory sciences. MCRI has a highly translational focus. Over half of the 70 research groups leaders are clinically trained and the institute is embedded within the Royal Children's Hospital (RCH), the major specialist paediatric hospital in Victoria treating an average of around 35,000 inpatients per year and close to 230,000 outpatients. The RCH campus, which includes the University of Melbourne's Department of Paediatrics, was highlighted in the recent McKeon review as an example of how integration of research and healthcare delivers better health outcomes.

MCRI strongly supports research commercialisation and industry engagement, seeing these as key components in advancing work at the institute towards an outcome that will yield societal and financial benefit. For example, the RCH campus has established a specialist paediatric clinical trials centre leveraging the strengths of the campus in trials governance, ethics, statistics, trial design and conduct. This has attracted significant industry interest with 56 industry-sponsored trials currently underway.

The institute has a diverse pipeline of projects across therapeutics, devices, genomic diagnostics, digital health (including mobile apps, repurposing of commercial devices like the xbox kinect for application in health etc), educational resources and tools, and research/technology platforms. MCRI, through its Commercialisation & Legal office, actively pursues translation and commercialisation of projects in the pipeline (See Box 1). The office signs approx. 400 contracts each year, with a large proportion of these focused on industry engagement (eg confidentiality, contract research, collaboration and material transfer agreements).

MCRI wholly owns the Victorian Clinical Genetics Service (VCGS), a clinical and laboratory genetics service with an emphasis on translating the latest research discoveries into innovative clinical care. VCGS provides its clinical services in Victoria, Northern Territory and Tasmania, and through 6 diagnostic laboratories located at MCRI offers genetic testing nationally and internationally with a growing business in the Asia-Pacific region. More than 170,000 specimens are received each year. A large proportion of VCGS's diagnostic services portfolio is now based on tests that have been developed at the MCRI and this is likely to increase in the near future. Through this model, MCRI commercialises its tests by bringing them directly to market via a wholly owned subsidiary. MCRI has significant activity in the emerging area of Digital Health. In this case the institute can take the product directly to market via a platform

such as the iTunes store. Emphasis is then placed more on marketing and sales than on finding an industry co-development partner and licensing, while IP protection is often via copyright and trade secret.

**Box 1: A snapshot of the MCRI commercialisation portfolio**

**Rotavirus vaccine** – Following the discovery of rotavirus as the cause of severe gastroenteritis by Professor Ruth Bishop at the RCH campus, work has been undertaken to develop a vaccine. Each year more than 500,000 children under 5 years of age die due to rotavirus gastroenteritis, mostly in developing countries. The vaccine is in phase II/III clinical trials with support from the NHMRC, the New Zealand Health Research Council, the World Health Organisation, the Bill & Melinda Gates Foundation and collaborations with vaccine manufacturers, including Bio Farma in Indonesia, key to delivering a large scale commercial product.

**POSSUMweb** – an online support and teaching tool to help inform clinical diagnosis of dysmorphology syndromes in patients. Information including more than 30,000 images photos, Xrays, scans, diagrams, and histology has been curated over the past 30 years at MCRI and VCGS providing a rich unique resource. This year a licence and distribution agreement was signed with BIOBASE, a European biological database company that was subsequently acquired by global molecular diagnostics company Qiagen, making POSSUMweb available for research and clinical users internationally.

**GI Therapies** – GI Therapies was established as a start-up company in 2012 with \$2 million investment from the Medical Research Commercialisation Fund to develop a non-invasive medical device, Rhythm IC®, for the treatment of chronic constipation in adults and children. CC is a common symptom affecting over 80 million people worldwide which results in a significant impact on their quality of life. The company has designed and is now positioned to manufacture easy to use devices for gastrointestinal applications.

**New diagnostic tests** – a portfolio of new diagnostic tests are under development at the institute. One such example is for Fragile X syndrome, a genetic condition that causes intellectual disability, behavioural and learning challenges. The current gold standard testing for Fragile X is cumbersome and cannot predict specific cognitive and behavioural impairments in female carriers of the condition. Researchers at MCRI have developed a new test that overcomes these limitations that is now being finalised for incorporation into the diagnostic portfolio of the Victorian Clinical Genetics Service (VCGS), a wholly owned subsidiary of MCRI.

**New digital health technologies** – the institute has a rapidly growing digital health pipeline, incorporating mobile health apps, e-learning courses and re-purposing of gaming technologies for health applications. In collaboration with software development company Curve Tomorrow, MCRI is developing a platform for the assessment and rehabilitation of movement disorders in kids using the xbox kinect camera. This project has attracted international interest and recently won the Launch! Event at Health 2.0, the major digital health conference held in Silicon valley this year. This was the first time a non-US company won the event.

**Raising Children Network** - a not-for-profit company founded by MCRI, the Parenting Research Centre and the Smart Population Foundation. It provides reliable and scientifically validated information and resources online to help parents with the day to day decisions of raising children, and to help parents and carers look after their own needs. The content is developed and translated into everyday language so parents can understand and use it in a way that works for them. This provides a powerful and engaging vehicle to translate research into direct benefit to the community, attracting several hundred thousand unique visits/month.

We acknowledge Australia's poor ranking against other OECD countries in industry-academia collaborations, including researcher experience in an industry setting, and support exploring

mechanisms to improve this. However, it must be noted that critical mass and co-location play important roles, both of which Australia is lacking. In recognising this, MCRI has established a collaboration with a software development company that has resulted in rapid growth and development of a pipeline of digital health technologies at the institute, and a rapid increase in researcher engagement and interest in the area. The key to this success was the co-location of the company within the institute so that there was regular interaction and over time cultural barriers were removed and relationships established. There have also been enormous benefits for the company that has seen the number of staff double in 12 months and has led to a strategic focus on digital health (see Box 2).

***Box 2. MCRI's approach to digital health innovation and product development***

MCRI has formed a strong collaboration with software development and innovation company Curve Tomorrow to build a pipeline of digital health products. This collaboration, now into its second year, has yielded significant success with more than 30 products in development and strong interest and engagement from researchers and healthcare professionals across the RCH campus. This collaborative model has sparked national and international interest, given the challenges in breaking down barriers between different industry sectors (IT and health). A key differentiating factor is the resulting environment: a tech company within a medical research institute that is embedded within a major tertiary hospital. The partnership has also resulted in national and international awards including the Launch! Event at Health 2.0, the first for a non-US company, and a State Merit iAward. Key elements of the collaboration include:

**Co-location and critical mass**– MCRI has allocated space for Curve Tomorrow at the institute so that the company spends significant time (now more than 90%) at the institute, facilitating regular interaction with the researchers. This has played a key role in breaking down cross-cultural barriers and has helped create an understanding of the respective business areas.

**Multi-disciplinary skill sets** – a project team will now often consist of software engineers, designers, engineers, medical researchers and clinicians, with additional skills like regulatory affairs and health economics sourced externally as required. This allows projects to design-in key aspects and requirements from the outset rather than retrofit. It also informs appropriate costing and timelines for grant proposals and business plans.

**New technologies and concepts** – the relationship allows the fusion of cutting edge medical research with cutting edge digital technologies, that MCRI would otherwise not be aware of nor have the skills to evaluate.

MCRI welcomes the review of government mechanisms that support translation of public research into commercial outcomes. MCRI sees that the Commonwealth Government can positively impact commercialisation through areas such as funding mechanisms, policy development and implementation, stable and attractive regulatory frameworks, and incentives to attract industry investment .

## MCRI response to discussion paper proposals

### Creating stronger incentives for research-industry collaborations

#### a) Funding mechanisms

We support incentives to encourage greater collaboration between researchers and industry. Funding schemes like the ARC linkage grants and NHMRC development grants attract industry investment and commitment of resources towards development of new IP and technologies. However, there are limitations with the current grant schemes, including:

- Limited access – MRIs cannot access the ARC linkage grants scheme and are therefore overly dependent on NHMRC Development Grant funding;
- Long lead times – NHMRC Development grants have only one funding round per year and take 5-6 months from submission to outcome;
- Low success rates – This together with the long lead times can disadvantage product development (particularly in fast evolving areas like genomics and software development) and can hinder industry engagement;
- Low risk tolerance – Partly driven by the limited budget, successful grants tend to be lower risk, more developed projects in the well established drug discovery and medical device sectors, with less emphasis on emerging areas like digital health.

We propose the following to address the limitations outlined above:

**Recommendation 1:** Double the NHMRC Development grant budget and introduce two funding rounds per year

**Recommendation 2:** Enable MRIs to access the ARC linkage grant program

**Recommendation 3:** Diversify the grant panel skill sets to include emerging, less developed but high growth areas like digital health

#### b) Recognising industry-relevant experience

We acknowledge that commercialisation experience is not adequately recognised in competitive grant schemes and researchers that are actively involved in commercial activity can have delayed publication outputs that impacts their chances of success in peer-reviewed funding.

It is important to ensure that commercialisation experience extends beyond “industry experience” to include entrepreneurial researchers who have been involved with or led development of products without industry assistance. In the case of researchers at MCRI this could include:

- Development of diagnostic tests that are subsequently incorporated into the product portfolio of the Victorian Clinical Genetics Service, a wholly owned subsidiary of MCRI. These diagnostic tests will be offered on a fee-for-service basis and will often be used by international groups.
- Development of new apps for mobile devices that will be taken to market via the Apple iTunes or Android play stores. These include paid apps, as well as free apps that can have associated services for a fee.

**Recommendation 4:** Recognition should be given to experience in commercialisation, and metrics should extend beyond patent filings and licensing to include activity in product development and commercialisation in other sectors like digital health and genomics, where patents may not always be an appropriate form of IP protection.

**c) Consolidation of existing programmes that focus on collaboration with industry**

MCRI strongly recommends that existing programmes are **not** consolidated. Each of the funding schemes have unique and complementary roles. Consolidation would mean an over reliance on a small number of schemes, fewer funding rounds and would also likely impact on turnaround times from submission to outcome. Further a single grant scheme is unlikely to appropriately address the needs of different industries, eg. Software development versus drug discovery., or different organization types, eg. SMEs versus large multinationals

**Recommendation 5:** Funding schemes are **not** consolidated.

**Supporting research infrastructure**

MCRI supports long-term research infrastructure investment and would encourage leveraging of investment where possible and the allowed use of funding to extend to specialist personnel.

**Recommendation 6:** leveraging state investment and where appropriate, industry investment;

**Recommendation 7:** funding to support overall facility operational costs, including specialist personnel.

**Providing better access to research**

**a) strengthen IP guidelines for researchers**

MCRI strongly recommends that IP guidelines are developed and implemented by each research organisation rather than relying on an overarching government IP guideline. IP guidelines will depend on the nature and core business of an organisation. A one size fits all approach will not be useful or practical, and risks being a distraction.

MCRI has a well-established IP policy in place providing clear guidelines on IP ownership, management and commercialisation, including the role of the commercialisation office and how royalties will be disseminated to inventors.

**Recommendation 8:** Each organisation should be responsible for their own IP guidelines. These could be based on general guidelines provided by the government.

**b) examine the potential to link research funding to the dissemination of IP**

Further detail is required to provide meaningful comment on this proposal, particularly with regards to what is intended by “dissemination of IP”. In any case we urge caution in tying funding to commercialisation or sharing of IP.

IP is not static and continuously evolves during and beyond the life of a grant, while commercialisation-ready IP may require a number of years and several grants, particularly in health and medical research. Further, it can take some time to find a suitable commercial partner with an aligned portfolio and interest, before any negotiation on contracts or financial terms takes place. A scheme that ties funding to commercialisation of IP, or public dissemination of IP within a certain timeframe, risks forcing the commercialisation of IP too early and at a lower value. Instead, what could be explored is the concept of bonus or “top-up” funding for projects that have yielded a successful commercialisation outcome.

**Recommendation 9:** Explore a rewards based system that “tops up” grant funding or provides a bonus (for eg. for international travel to promote IP) instead of tying a grant to dissemination of IP.

**c) establish an online point of access to commercially-relevant research for business**

We do **not** support the concept of an online point of access to commercially-relevant research. A critical part of commercialisation is the establishment of relationships and an agile approach, where other IP or access to other areas of expertise at the research organisation adds value to the overall commercial package. This cannot be captured on an online platform.

There is also a risk that commercial partners who utilise an online point of access and do not find a project of interest would not explore further opportunities in Australia, a significant lost opportunity to establishing contacts, building a relationship and entering into broader discussions.

Cost of maintaining the site and ensuring information on the site is up to date and relevant would be significant. Instead, we would suggest that funding could be used to support researchers in “pitching” their IP to potential industry partners nationally and internationally.

**Recommendation 10:** An online point of access is **not** pursued and instead resourcing is put towards supporting researchers to promote their research and IP nationally and internationally.

**d) develop a whole of government policy to open up access for business and the community to publicly funded research**

The current policies of the NHMRC and ARC to make the results of research publicly available within 12 months of publication are sufficient. These recent policy changes have resulted in a significant administrative burden on research organisations, and we do not recommend any additional policy requirements at this stage.

**e) IP toolkit**

A better understanding of the concept and purpose of an IP toolkit is required.

**Increasing industry relevant research training**

We support increased training in commercialisation for PhDs, postdocs and research leaders and see this as a key role of the commercialisation offices in MRIs and universities.

MCRI’s Commercialisation & Legal office runs a number of training, internship and educational schemes for researchers at all levels across the organisation. There are also incentives for researchers involved with commercialization (see Box 3).

We make two recommendations to increase researcher engagement and upskill in commercialisation-related activities:

**Recommendation 11:** Create an NHMRC development grant-like scheme for early career scientists and students to support proof of concept and product development work that would lead to commercialisation outcomes. This would build real life experience and help foster a future generation of commercialisation-savvy researchers. The scheme could also focus on high risk new to world type research.

**Recommendation 12:** Provide support in the form of travel awards to researchers and commercialisation offices to facilitate international discussions with potential national and international partners.

### ***Box 3. Training, education and incentives in relation to IP at MCRI***

MCRI recognises that IP created as a result of research activities is a significant and valuable asset, which must be responsibly managed to support the mission of the MCRI and acknowledge the inventors. The translation and/or commercialisation of IP supports MCRI's objectives because it allows for MCRI's knowledge and IP to be transferred into health outcomes. In order to achieve these objectives, MCRI employs a two-pronged approach: 1. Providing IP and commercialisation training and education, and 2. Evaluating and incentivising activities related to translation and commercialisation. Both of these undertakings are supported by MCRI's Commercialisation and Legal Office and are discussed in more detail below:

#### ***1. IP and commercialisation training and education program***

MCRI provides a comprehensive IP and commercialisation training and education program to staff and students at all levels across MCRI, and the broader RCH campus. The objective of this program is to build engagement and awareness of IP capture, translation and commercialisation and consists of 3 main themes:

a) IP Seminar Series: This seminar series is delivered in conjunction with intellectual property firm FB Rice and is targeted at senior post-doctorial researchers and laboratory heads. The seminar series aims to provide an in depth understanding of how to identify and handle the IP embodied in their research and explores subjects such as the tension between patenting and publishing, inventorship and a patent searching workshop.

b) Molecules to Medicines (M2M) business development internship program: MCRI supports between three to five interns a year through the M2M program (<http://molecules2medicine.org/>). This program is targeted at post-doctorial early career researchers. A key component of this program is on-the-job training provided by the Commercialisation & Legal Office, which involves the interns in the current Office projects, including practical work that provides the interns with hands on commercialisation experience.

c) Targeted presentations: Presentations on IP and commercialisation are given to specific research themes, groups and collaborative initiatives across the campus. For example, tailored presentations are delivered to PhD students, at the Royal Children's Hospital Grand Rounds series and on the NHMRC Development Grant scheme.

#### ***2. Performance evaluation and incentives***

MCRI's research is divided into five Research Themes. The performance of the Themes is evaluated annually through a review of research performance data. Through this process, each Theme is allocated a research performance score and internal funding is allocated on the basis of the performance evaluation

results. IP, contracts and commercialisation activities are included in the assessed research performance data, thereby contributing to the Theme's performance score and allocation of internal funding.

MCRI also provides incentives for researchers involved in commercialisation activities through the operation of its IP Policy. Under this policy, the effort and involvement of researchers in commercialisation activities is rewarded through return of a share of revenue received by MCRI from the commercialisation of their research.

### **Measurement of outcomes**

Any new metrics to measure (and reward) commercialisation should extend beyond patenting activity and licensing, and include launch of new products to market (eg. Apps via the iTunes or Play stores), or through wholly owned services or facilities.

In addition, while measurement of knowledge transfer and engagement with industry is important, this should be considered in the context of the many other pathways to research impact, including engagement with end users from other sectors. In many cases this engagement can still result in direct or indirect economic impacts, as well as other public good benefits. Examples include translating research findings into improved guidelines for clinical practice, new methods to improve the cost-effectiveness of health services, and policy advice to government agencies or not-for-profit organisations (e.g. in emergency services, health policy, improved community service provision).

### **Capitalising on the Medical Research Future Fund**

MCRI supports a role for the MRFF in helping drive the translation and application of health and medical research in Australia and would encourage that the MRFF is used to drive translation via both commercial and non-commercial avenues.