



THE UNIVERSITY OF
MELBOURNE

Response by the University of Melbourne to the Victorian Health and Medical Research Strategy

Discussion paper



Executive summary

The University of Melbourne welcomes the opportunity to contribute to the review of health and medical research currently being undertaken by the Victorian Government. We are Australia's premier university for health and medical research, located in the greatest concentration of biomedical researchers and clinicians in Australia, the Melbourne Biomedical Precinct. We educate more health professionals, graduate more research and higher degree students and attract more nationally competitive funding than any other Australian university. Out of the 54 institutions receiving NHMRC funding in the 2014 grant rounds, we received the highest proportion (13.4%) of new grants funded. Medical and Health Sciences at the University of Melbourne also achieved the maximum world rating in the Excellence in Research for Australia Report, which reinforced our position as the leading biomedical research university in Australia. We are proud of our achievements in discovery research, translation and commercialisation in health and medical research that have made a difference to Australia and the world. Snapshots of these outstanding achievements are presented at Attachment One.

Victoria's health and biomedical research ecosystem is a complex yet vibrant mix of hospitals, medical research institutes and universities. Its physical and intellectual capital plus the incredible dedication of researchers, clinicians, nursing and allied health professionals, educators, students, volunteers, administration and professional staff are a national asset that must be sustained and nurtured.

Our response is broadly structured under the headings provided in the Government's Discussion Paper. We provide further insight from our academic and clinical expertise, plus our experience over many years in addressing many of the issues identified within the Discussion Paper.

There are many opportunities for improvement and development of Victoria's health and medical research system and capabilities, including those identified within our response. The University of Melbourne welcomes the opportunity to discuss any part of this submission further.

A summary of our key recommendations and observations is provided below:

Integrating research, education and healthcare

- Greater coordination and collaboration and financial support is required to achieve the full potential of the Melbourne and Monash Academic Health Science Centres;
- Capability development (skills, career paths and critical mass) for health services and health economics research and translation is critical.

Developing a convergence science capability

- State investment is needed to develop critical mass in convergence science and biomedical engineering, and support for convergence science projects that fall between the ARC/ NHMRC funding interface; The University of Melbourne is preparing a confidential submission for State consideration in relation to developing medical technology capability in Victoria;
- A roadmap and implementation plan for precision health and medicine is required; The Melbourne Genomics Health Alliance has been influential in positioning the state for this purpose.

Optimising big data and informatics

- Investment in clinical genomics, health informatics, bioinformatics, biostatistics, computation biology and data science capability is a State priority;
- The State must develop an integrated electronic medical records management system across all hospitals that is accessible to both clinical and research sectors;
- Ongoing development is required to link and integrate data management platforms such as GRHANITE and BioGRID.

Implementing a world-leading clinical trials system

- Increase awareness amongst the community and the medical community of clinical trials and develop a lay-person user-friendly website to search for clinical trials;
- Develop a single up-to-date database capturing all clinical trial activity in Victoria;
- As part of a Clinical Trial attraction strategy, negotiate a single cost structure for trials; and ensure that there are CT beds in public hospitals;
- Invest in core biostatistical and trial design capability at the Melbourne and Monash Academic Health Centres.

Developing the next generation health and medical research workforce

- Invest in scholarships, fellowships and international exchange programs for the Health and Medical Research (HMR) workforce and in priority research areas;
- Provide additional support for science-awareness programs in schools and the community;
- Support women in biomedical research by incorporating the Athena Swan Charter into the State's gender equity program.

Advancing international collaborations, industry-research engagement and innovation

- Establish a Proof of Concept Fund to develop promising intellectual property further along the value chain with operational funding provided by the State; The University of Melbourne is negotiating with other Universities to create a Proof of Concept fund and may seek State support for this venture;
- Develop new models for pharmaceutical drug development; The University of Melbourne is scoping an opportunity in this area;
- Leverage bilateral trade links and trilateral relationships through strategic funding in priority areas with international collaborators;
- Attract talented researchers and clinician-researchers back to Australia through ongoing support for VESKI.

Securing development and commercialisation opportunities

- Attract R&D offices of multinational corporations to Victoria.

Philanthropic sector engagement

- Encouraging philanthropic investment in strategic areas and commonly neglected areas.

1. Priorities for the State in Research and Research translation

Victoria is Australia's leading state for biomedical and clinically informed health research in Australia as evidenced on numerous occasions through its success in the nationally and internationally peer-reviewed National Health and Medical Research Council (NHMRC) schemes, the award of two Advanced Health and Research Translation Centres within the State and comparative statistics on spin-out companies in medtech.

Priorities for research

The University of Melbourne considers that the priority areas of future focus for health and medical research should be addressed in terms of health priorities and core capabilities:

Health priorities

- Neurology and Mental Health;
- Immunology and infection;
- Cancer;
- Child Health.

All outcome areas are of equal importance and map directly to Victoria's strengths and needs.

Core capabilities

- Clinical and public health genomics;
- Biomedical engineering and innovation;
- Health services, health economics and health system performance research;
- Platform technologies;
- Clinical trials;
- Health informatics and data science.

The importance of translation

The Melbourne Biomedical Precinct, located in Parkville with the University of Melbourne at its heart, has led the translation of its research into national and international practice over many years. Outstanding exemplars in research and its translation by University researchers are provided at Attachment One.

These translation successes have taken, in some cases, many years to come to fruition, and have been supported by state, national, international, commercial, philanthropic and international funding. Successive State Government policies have been particularly crucial to this success. The University of Melbourne urges that ongoing support for translation in the health priorities of Neuroscience and Mental Health, Immunology and infection, Cancer and Child Health continue.

2. Integrating research, education and healthcare

Academic Health Science Centres

Given the ongoing development of the academic health science centre (AHSC) model internationally; the social and organisational processes for their effective leadership, organisational development, and tripartite mission of integrating research, education and healthcare are still being investigated and understood. What is known is that AHSCs tend to differ significantly in their internal clinical-managerial arrangements and organisational cultures, which variously influences their strategies and institutional incentives.

As noted in the HMR Discussion Paper, the Melbourne Academic Centre (MACH) for Health and Monash Partners (MP) have achieved national recognition under the NHMRC's Advanced Health and Research Translation Centre program. MACH was established as a joint venture (JV) between its 18 partners in 2014 with the goals of enabling collaboration to deliver better health outcomes for Victorian communities, providing improved educational support and driving the translation and application of health research into the delivery of healthcare. MACH is governed by a representative board from the healthcare, independent medical research institute and university partners. It represents the largest consortium of its type in Australia. Monash Partners, although a smaller consortium, plays a similar role for Monash University and its partners. In both cases the programs embrace the tripartite mission of healthcare, research and education so effectively implemented internationally in places like Johns Hopkins University.

Individually both MACH and MP provide a degree of critical mass and coordination that accommodates the majority of the State's population and major healthcare facilities. The two Centres recognise the importance of working together for the benefit of the health and medical research system and recently signed a Memorandum of Understanding to promote greater levels of collaboration between the two centres. Indeed, the University of Melbourne's single most important partner measured by co-publications is Monash University and *vice versa*.

Based on learning from international AHSCs (and related Academic Health Science Networks), Victorian AHSCs would benefit from policy and economic incentives to drive collaboration – not just internally within the AHSCs (enabling research, resources and personnel to be mobilised across their internal organisational boundaries) but also with other Victorian AHSCs in delivering more complementary and coherent 'whole system' strategies.

We consider that the State Government has an opportunity to leverage the potential of these two centres of research and translation excellence in a number of ways:

- Firstly, through the provision of direct pro-rated financial support to each centre, the State can drive collaborative activity within the AHSCs in a range of health and medical research areas. To date these centres have been funded exclusively by the collaborating partners. The provision of ongoing funds to expand the operation and scope of these centres would enable both the MACH and MP to become the 'go to' organisations for collaboration with the largest two biomedical precincts in the country. These resources would provide the critical glue to enable the Centre partners to work together - at the moment, there is currently strong goodwill within each of the Centres but the current funds provided by Centre partners are constrained. The Melbourne Biomedical Precinct at Parkville is developing a roadmap that outlines how judicious investment by the State could be critical to helping the precinct achieve its full potential.
- Secondly, the State has the opportunity for the first time to catalyse selected activities across both centres by supporting collaborative programs where these are a natural fit across these centres. The University of Melbourne strongly supports the aspirations of both the MACH and MP to work together for the benefit of patients in Victoria and thus requests that the State supports such endeavours. Areas for immediate action could include the standardisation of clinical trials, ethics and governance processes across the State, a public awareness campaign regarding the potential value to individuals of being involved in clinical trials, the development of the Victorian population's level of health literacy, with specific emphasis on the most appropriate and expedient use of our health system, and the agreement on and coordination of significant areas of infrastructure and investment to avoid duplication.

Collectively, the MACH and MP provide the State with the capacity to drive reform and best practice in ways inconceivable when organisations are engaged individually. The leadership of both programs, and thus the bulk of the State's education, research and healthcare leadership are supportive of a more collaborative and internationally competitive approach.

Health Services Research

Health Services Research is of vital importance to the State. We support the definition of health services research provided on page 12 of the Discussion Paper, but suggest that it is appropriate that it is broadened to consider questions of access to health care and the structure of the health care system:

Health services research encompasses a range of activities such as evaluation of the quality, safety and cost of healthcare, assessment of healthcare needs and access to health care, measurement of health outcomes, evaluation of healthcare improvements, review of the allocation of healthcare resources, and examining the financing and organisation of health care.

In this context, the University recommends that the **priority areas for Health Services Research** in Victoria, and indeed nationally, are:

Cost drivers, funding and incentives: There is an ongoing need for recognition that achieving better outcomes across the health system requires a focus on the role of financing and incentives, on access and equity, on utilisation of health care, on the behaviour of agents in the health system (be they consumers, providers, institutions, funders or policy makers), and on the impact of institutional arrangements and incentives created by the funding and organisation of health services. For example, while new medical technologies can offer ground-breaking health benefits, they cannot properly contribute to an efficient health system unless they are funded and delivered in a way that facilitates their uptake and provides incentives for their appropriate use.

Priorities for research therefore include the examination of major health cost drivers, their rationale for use, variation analysis in service levels against the costs of major aggregate drivers (clinical conditions) and how new services and technologies should be funded. This will enable us to understand the causes of unwarranted clinical

practice variations and eliminate 'waste', low value care, or inefficient care. It also considers the incentives that should be given to providers to encourage uptake and how patients' and providers' behaviours can be modified to encourage uptake of new services and technologies.

The organisation and delivery of health care: Similarly health services research focused on service delivery and organisation is significantly under-developed, especially compared to comparable health systems in Canada and the UK (which have stronger critical mass of health services research investigating health care organisation and delivery at both systems and organisational levels).

New and innovative models of care: This requires exploration and trialing of innovative healthcare models that are more efficient and cost-effective. These also have greater emphasis on primary or secondary prevention by mobilising primary care or community preventative interventions in place of more expensive and less efficient hospital-based solutions.

In association with these priorities, it is important that there is an increased emphasis within the health system on preventative healthcare, recognising the growing epidemic of chronic non-communicable diseases (NCDs). This is necessary to reduce the use and cost of hospital care through stronger management of chronic disease in primary care settings, and through stronger links between acute and sub-acute care. Understanding the referral patterns and decisions of GPs is fundamental to this. Further, applying complexity and systems theory is necessary to address the interactions between social and economic determinants, individual capacities, and health services in their prevention and management of NCDs.

A systems approach also incorporates recognition of the linkages between local, national, regional and global health systems. It recognises that there is increasing connection between Australian health systems and services and those of neighbouring and regional countries; and the need for closer cooperation between nationally focused and globally focused Victorian academic health service / systems research centres, and research centres in the Asia Pacific region.

Capacity and skills development

In order to address these priority areas, it is vital that the State invests in the development of capability in health services and health economics to sustain critical mass across research, clinical and government sectors, and engages with existing expertise. Victoria has three strong health economics groups (Melbourne¹, Monash, Deakin) with strong international reputations, however there is substantial opportunity for further engagement with Government and the health sector. Each group has complementary interests that span economic evaluation and health technology assessment, health policy, health systems and incentives, and the economic and social determinants of health. These interests are central to improving health in Victoria. Further investment in health economics and health services research in Victoria has the potential to deliver large gains in population health by adding value to what already exists.

The important role for developing skills in health economics research and health services research in 21st century healthcare was also highlighted in the McKeon Review. There are significant shortages of trained health services researchers with discipline background in high level quantitative sciences (epidemiology, biostatistics, mathematical modelling, economics) and qualitative methods. For example, there is currently very little training of economists across the State, especially economists with expertise in health. Victoria relies heavily on junior and senior health economists from other countries, which is not always sustainable. Even for early career professionals and researchers, there are poor and unstructured career trajectories. In addition, there are few senior health economists working in the Department of Health and Human Services that have the capacity to provide appropriate supervision.

It is recommended that governments build capacity in health services and health economics disciplines that will deliver health system impact. The State should invest in the development of structured career paths where trainee health service researchers and health economists move between government, hospitals and the three universities. This approach requires that there is capacity within government through senior health economists and health services research leaders who are able to supervise emerging leaders. The Victorian higher education sector can assist in building capacity through secondments and training.

In addition to addressing skills shortages, efforts should be focussed on providing incentives for Victoria's three leading universities for health services research to work collaboratively with Government in the priority areas of *cost, drivers and incentives; the organisation and delivery of health care; and new and Innovative models of care*. Given the strategic importance to the State, direct funding investment is appropriate via new funding schemes in health services research and health economics, in part to understand, assist and evaluate clinical translation.

¹ See <https://www.melbourneinstitute.com/health/> and <http://mspgh.unimelb.edu.au/centres-and-institutes/centre-for-health-policy> for details of relevant capability at the University of Melbourne.

3. Developing a convergence science capability

Healthcare is under pressure on many fronts: the growing prevalence of chronic diseases and the changing constellation of disease patterns are contributing to mounting pressures, and costs, on health systems around the world. Further, new knowledge and the convergence of technologies are disrupting traditional approaches to the delivery of health services and the relationship of health services providers and healthcare consumers. Individuals are becoming increasingly empowered using their own personal data to inform decision making. The boundaries of health and wellbeing have already expanded beyond clinical care into exercise, mobility, preventative and lifestyle products.

The University of Melbourne welcomes the Victorian Government's recognition of the importance of convergence science in Victoria. Biomedical engineering and precision medicine, particularly in the context of clinical and diagnostic genomics, are two very relevant examples of convergence science where the State has outstanding capability and potential. They also represent significant opportunities for the development of new knowledge-intensive industries in the State.

Genomics and Precision Health

The University is of the view that it is important to reframe the concept of *precision medicine* to *precision health and medicine*. For example, the new "omics" technologies, especially genomics, have the potential to stratify unaffected people into categories based on their future risk of developing cancers. This information could be used to personalise screening protocols, and also inform risk management strategies. Better means of risk categorisation are being developed that take into account multi-generational family history, genetic and epigenetic markers of risk, phenotypic markers of risk (e.g. mammographic density for breast cancer, skin type and naevi for melanoma) and environment and lifestyle factors. Victorian scientists are among the world leaders in these new developments using Australian cohorts developed two or more decades ago and similar international cohorts. The roles of GPs and cancer family clinics in being drivers and focal points for precision population health are currently being trialed in Victoria. *Precision health* should be a key pillar of the State's preventative health strategy.

The recent State and federal government investments in genomics represent a crucial step in transforming our ability to not only diagnose and treat a variety of illnesses, but also to re-align the health care sector around the patient. In particular, the Government's support for the activities of the Melbourne Genomics Health Alliance (MGHA), a Melbourne-wide initiative with its origins in the Melbourne Biomedical Precinct, are to be commended. This initiative will be critical in demonstrating the clinical utility of genomics to the State.

To fully benefit from this investment, there will also need to be investment in other areas that enable precision medicine to achieve personalised medical outcomes. It is important that these investments are made strategically. We recommend that the Victorian Government develops and implements a focussed roadmap that sets out the requirements to realise the potential of precision health and medicine, for example considering issues of infrastructure requirements, health economics and 'who pays', workforce upskilling and development, and patient-centred issues such as education and awareness for the Victorian community and general medical practitioners in order to understand the benefits of such testing, privacy and confidentiality issues in relation to access and use of personal information. Data management from all aspects is essential, from issues of data storage, to the need to develop consistent and interlinked electronic health records that can engage strongly with the State's clinical activities and strengths in biomedical and health research.

It is also important that we look at this field with an international mindset. Fortunately, Victoria is already demonstrating international leadership through its involvement in the Global Alliance for Genomic Health (GA4GH). Support for ongoing engagement and cooperation with international nodes is essential to take advantage of the latest technologies and methodological approaches.

Convergence science and biomedical engineering

As discussed already, Victoria's biomedical and health sector is state-of-the-art in many respects. The opportunity now presents for Victoria to exploit its potential and deliver economic outcomes by leveraging the convergence agenda in biomedical engineering and innovation. This is timely in an age where unprecedented technological advancement has led to greater demand for deep expertise. Biomedical science and engineering will play an instrumental role in addressing future health challenges. Melbourne has the right mix of research institutes, hospitals, a highly skilled workforce and strong translation capability to make it the MedTech and biomedical engineering leader in Australia and the Asia Pacific.

To achieve this, the blueprint that has been successful in other biomedical domains should be applied to biomedical engineering to link fundamental research with technology capability, clinical and general health practice and an

entrepreneurial culture. In doing so, Victoria will see a vibrant economy underpinned by jobs growth in knowledge-intensive industries.

To achieve this outcome, it is imperative that critical mass in biomedical engineering and innovation is developed in areas of existing clinical and research concentration across the state. It is important that the University of Melbourne, with its record in health, biomedical research, science and engineering, also contributes to the biomedical engineering and medical technology agenda by coalescing, catalysing and leveraging its substantial, multidisciplinary research strengths, clinical leadership and networks for the benefit of Victoria.

Biomedical Engineering and Innovation at the University of Melbourne

To this end, the University is in the process of establishing a new Institute for Biomedical Engineering and Innovation. This Institute will provide the opportunity for the University of Melbourne, its clinical and its industry partners to systematically focus and build on our world-class strengths and capabilities in medicine, sciences and engineering. The Institute will have its geographic focus in the Melbourne Biomedical Precinct at Parkville, with RMH, the Women's, and the Children's Hospital at its core, but also extending via the Western Health network and the Austin Hospital. We expect that it will deliver health and medical technology innovations that will help transform Victoria and Australia's approach to healthcare and contribute to the development of future knowledge-intensive industries and jobs for Victoria. The University considers that there is substantial opportunity to develop new medical solutions for pressing health care needs through a process of clinically driven biomedical engineering research and innovation.

The Institute will be complementary to other biomedical engineering initiatives and precincts across the State, in particular networking and activities such as the Convergence Science Network and the establishment of the Monash Institute of Medical Engineering (MIME) at Monash University's Clayton campus. The programs and activities of the Institute will also be aligned and integrated with the \$180M capital works program of the Aikenhead Institute for Medical Discovery.

It would also be of value to the State to strategically support basic research projects in biomedical engineering. These projects often fall into the funding crevice between ARC and NHMRC funding: the ARC is reluctant to fund them where there are near-term links to health and medical outcomes, while they do not fare well in regular NHMRC funding programs as they do not have enough of a health and medical research focus.

4. Optimising big data and informatics

Optimising big data and informatics

Data is the new currency of 21st century healthcare. As summarised in the Discussion Paper, a strategic system-wide approach to data collection and utilisation is essential to inform decision-making, delivery of patient-centred health services, for measuring performance and for research. Yet the management of this asset is generally poorly coordinated, accessed and leveraged across the Victorian and national health systems. Data is often incomplete or not captured in a usable format, or is bound by regulations, culture and practices that prevent data quality and sharing. It is vital that the State invests in strategy, technological platforms and training to enable data to be shared and exploited across all components of the health system, that is, research, clinical, hospital and allied and community health sectors.

To achieve the outcomes for patients, policymakers, providers and associated stakeholders that are derivable from better use of health and biomedical data, overall State leadership is required via a coordinated and networked approach that engages and supports clinicians, researchers and health consumers across Victoria.

Underpinning platform development is the imperative to agree on data standards, metadata and collaborative approaches to data federation and sharing. There are several global initiatives in the area including National Institutes of Health 'Big Data to Knowledge (BD2K)², the Global Alliance for Genomics and Health³ and the European ELIXIR⁴ initiatives. It is vital that Australia participate in these initiatives as a first class partner. For example, the EMBL Australia Bioinformatics Resource, hosted at the University through the Victorian Life Sciences Computation Initiative (VLSCI), has commenced discussions with the BD2K and ELIXIR initiatives to explore options for formal and informal collaborations. Victoria is home to unique information assets such as GRHANITE⁵ and BioGRID Australia that are

² <https://datascience.nih.gov/bd2k>

³ <http://genomicsandhealth.org/>

⁴ <https://www.elixir-europe.org/>

⁵ <http://www.grhanite.com/technologies/>

supporting biomedical and health research. Additional investment in such platforms will leverage the significant value they represent and provide enhancements so that they are able to deliver expertise for all of the State.

Data security continues to be a major concern, as is ability to access external resources or upload data from health facilities in Australia, many of which are restricted by firewalls etc. Because of our deep expertise locally, there is an opportunity for Victoria to take a lead in developing bioinformatics tools, including text mining of historical records, and workflows that would become standard across Australia and adopted internationally, resulting in more integrated and efficient data comparison.

Investing in health informatics/ bioinformatics capability

The State has provided significant strategic support for building the computational and informatics skills base, for example, VLSCI, which has demonstrated national and international leadership and has developed a suite of tools for genomics, bioinformatics, molecular dynamics and computational bioimaging.

Bioplatforms Australia have recently conducted a survey of Australia's provision of bioinformatics tools and resources, which affirms that strategically concentrating computation and analytical expertise, such as VLSCI, is the preferred model for success in bioinformatics. It is noted within the draft Report that:

In general and outside of a number of high performing teams, insufficiently skilled and insufficiently resourced application of sophisticated and constantly evolving methods [of bioinformatics] is having an impact on 'omics' related science outcomes.

In that context, it is of critical importance that investments in developing and disseminating best practice methods and tools occur in parallel with technological, e-infrastructure and data management investments. While there is much international progress in this domain, and it is essential that Victorian development is tightly networked with such work to avoid duplication and maximise efficiencies; in some specialist fields, for example microbial genomics, there are no commercially available tools for high throughput data analysis. Accurate, high throughput bioinformatics tools that can be shared across facilities and jurisdictions are critical to the successful implementation of microbial genomics in Australia.

Upskilling, education and training for dedicated bioinformaticians and informatics-literate health professionals are paramount for future success. This can be achieved by co-supporting specialist training programs and providing incentives for participation. The University recommends that there is support for:

- Postgraduate programs in Bioinformatics and Computational Biology that emphasise interdisciplinary training and include embedded research placements - one example of this approach is the University's successful MSc (Bioinformatics);
- Software engineering programs to create a workforce that can develop bespoke software solutions for data capture and facilitate access that are ready-made to integrate with existing State and national health e-platforms;
- Short course skills training in genomic methods for current practitioners (both technical and clinical);
- Promotion of career pathways for bioinformaticians and clinical workers in this space, noting the emerging need for creation of specific positions for bioinformaticians to work in clinical roles; and
- Attraction and recruitment of talented Australians currently working overseas back to Melbourne (for example through extending further the VESKI Initiative).

5. Implementing a world-leading clinical trials system

The Melbourne Biomedical Precinct, through the University of Melbourne, hospitals and medical research institutes, has an outstanding track record in conducting clinical trials. There are currently ~1000 clinical trials open across the Precinct, with 275 new trials approved in the 2013 calendar year and more than 5,000 patients currently recruited. Trials are undertaken across all phases ranging from first in human through to phase 4, with the majority being phase 2/ 3 CTN trials.

This success has been achieved in the absence of a coordinated and cohesive approach across the State; there is significant potential for further sponsored and investigator-initiated clinical trials development if the State establishes the requisite settings and infrastructure.

Community engagement and awareness of the Victorian Clinical Trials System

Increasing patient recruitment needs to start with increasing the awareness of the benefits in clinical trial participation across the general practice and private specialist arena. Multiple studies have shown that the 'Clinical Trial Effect' means that patients generally do better when in a clinical trial, even if on placebo, due to the additional care and attention they receive. The general public is not aware of clinical research and thus is reliant on information and guidance from their primary carer. Additionally there is an inherent 'anxiety' when it comes to contemplating medical research, which is only enhanced by the 17+ page Patient Information and Consent Forms. Increasing clinical trial awareness amongst primary care physicians and specialists solely in private practice can only help increase the awareness throughout the general population.

The development of a lay person user-friendly website to search for clinical trials could also increase awareness of clinical trials in the community. Using the live search function of the Australia and New Zealand Clinical Trials Registry is not user-friendly for lay people.

Reporting and repository for clinical trials data

There is no single accurate and up-to-date database capturing all clinical trial activity across Victoria. Without a single database, the State has little evidence to promote the region or to support our claims of research and clinical trials excellence. The Australian Research Ethics Database (AU RED) currently has limited hospital coverage and limited reporting capabilities. While further investment in AU RED may resolve some of these issues in future, there are a number of other initiatives underway. Identifying the best features of these initiatives and coordinating efforts would drive the efficient development of an optimal product.

As an example, the University of Melbourne, through the Melbourne Academic Centre for Health, is working to have all commercially sponsored and investigator-initiated clinical trials from the hospitals and medical research institutions affiliated with the University captured in the MACH Clinical Trials Database. Reports from the database will be able to show accurate study start-up timelines and recruitment for the 18 member institutions including eight of the major public hospitals in Victoria. Expansion of this database to cover the Monash and Western Alliance Academic Health Service Centres will showcase the full extent of clinical research in Victoria.

Best practice in clinical trials management

The newly established Melbourne Children's Trials Centre (MCTC)⁶ is an example of leading practice for clinical trials coordination and industry attraction. It is the largest trial centre of its sort in the southern hemisphere. It offers clinical researchers assistance with trial start-up, feasibility assessment, ethics submissions, budgeting, contracting and sourcing / connecting with research coordinators/nurses for trial conduct. MCTC also assists with endorsement for Investigator-Initiated studies whereby researchers can engage with senior clinical trial researchers and biostatisticians for help with protocol design and development in paediatric Medicine. MCTC also coordinates clinical trials with Monash as well as the other major children's hospitals in Australia.

The University of Melbourne's Clinical and Translational Sciences Platform (CATS) was established in 2014 to work with our hospital partners to provide support in clinical trials – dealing with health economics, statistics and best practice; CATS is intended to eventually serve the whole of the Melbourne Academic Health Science Precinct.

Opportunities for State and national coordination and collaboration

Further initiatives intend to share translational resources from the two major Melbourne universities towards clinical research and development to attract funding from government and private partners; such a critical mass is needed to attract international Biotech and big Pharma to the Melbourne precinct's translational capabilities.

Commonly quoted reasons for excluding Australia in international clinical research programs are ethics and governance delays and high per patient costs as compared to not only the emerging clinical research markets but also the USA and Europe. Patient recruitment and quality of data are rarely stated as reasons why studies are not conducted in Australia. Processes to streamline the ethics and governance processes through the NHMRC Good Practice Process Pilot study and the Research Excellence Initiative (REx) are focused on streamlining the processes of ethics and governance review to reduce delays in study start-up. With regard to costs of clinical research in Australia, the NHMRC is looking at developing a guidance document on a standardised costs structure. Australian Investigators need to be realistic and transparent with study budgets, preferably using standardised costs. Through collaborative research networks it would be ideal to negotiate one cost structure that will apply to all participating Australian sites.

⁶ <http://www.melbournechildrens.com/mctc/>

Attracting clinical trials to Victoria through better coordination and management

The Victorian Government has an important role to play by making it part of the remit of Victoria's public hospitals to participate in trials, ensure/coordinating a reserve of beds/ ward facilities/ investigation suites for clinical trials across the public health system as well as providing a "stamp of assurance" of quality design, process and value for money to prospective sponsors. By acting as a coordinating point of contact that promotes opportunities, offers streamlined processes in line with NHMRC best practice, provides consistency of costing and pricing and coordinates patient recruitment the Victorian Government can enhance the competitiveness of clinical trials within the State.

Through the Melbourne Academic Centre for Health (MACH), the University of Melbourne has already commenced the process of ensuring that the research sites of our 18 partner hospitals and research institutions are 'ready' for high quality clinical trials; and that sponsor companies can, in addition to direct contact, access all of these partners through a centralised contact point. Additionally, if a sponsor contacts a known investigator regarding a potential study, the sponsor is then exposed to all MACH partners with the assurance of the same commitment and quality as well as streamlined ethics and governance.

We have identified a number of initiatives to attract more clinical research to Australia. Through the Research Excellence Initiative (REx) the hospitals and research institutes affiliated with the University of Melbourne are collaborating to streamlining Ethics and Governance to provide a uniform process with increased efficiencies. An extension of this initiative is the coordination of a single database to track key performance parameters for research projects conducted across the MACH. As noted earlier, the current government AU RED database does not currently cover all clinical research activity, whereas the MACH database will collect data for all MACH partners and will be able to generate informative reports on timelines to approval and recruitment targets.

Additionally, it is important that clinical trial research coordinators are encouraged to promote knowledge sharing and mentoring. We support the establishment of a research coordinator working group which reviews processes and standard operating procedures to ensure the high quality of our areas of excellence are achieved across all clinical research units.

Investigator initiated trials

Investigator-initiated studies are important to advance medical and scientific knowledge and generate promising medical interventions. It is important that such trials are conducted as rigorously as possible; therefore their design and sample size is critical. This enables them to be funded through the national competitive grant system, ensures that they will be published in the highest quality health journals and increases the likelihood that their interventions and improved practices will be taken up within the State as well as national and internationally. In this context, it is important that investigators have sufficient access to quality biostatistical and study design advice. Currently, the provision of such expertise is under-resourced with demand for services greater than ability to supply advice. It would benefit the State to invest in this core capability at both the Melbourne and Monash Academic Health Science Centres. These centres are both excellent in health science research and should be utilised by the Victorian Government to facilitate investigator-initiated clinical trials.

Clinical registries

Clinical registries are important enablers for population-based and epidemiological research and support studies on the aetiology, prevention, early detection and clinical management of disease. Registries include patient data and specimens that are invaluable in developing new models of disease risk combining lifestyle, environmental and genetic risk factors. These models allow the development of screening programs, the identification of new genes and tailored prevention programs for patients. Traditionally these registries were set up as standalone databases in clinical treatment facilities, however there are now large-scale registries for common diseases such as cancer as well as cohort based registries such as the Australian Twin Registry. There is currently a lack of coordination amongst registries and enabling data linkages between existing registries would greatly facilitate their use for clinical trials.

The federated data sharing platform of BioGRID Australia Limited, specialises in making de-identified data, mostly clinical treatment outcome data which reside within hospitals, available to authorised researchers to dynamically extract and analyse. The availability of this platform has enhanced the use of registries for collaborative translational health and medical research, demonstrating the value of coordinating access to datasets. The introduction of electronic medical records would provide a means of expanding registries to capture a broader range of patients, which is essential to allow these registries to act as a source of potential participants for clinical trials. Any work on coordinating or expanding registries needs to address issues of patient privacy.

The largest medical database in Victoria is Medicare; however there is no use of this information to identify potential clinical trial participants.

6. Developing the next generation health and medical research workforce

Attracting and retaining health and medical research talent

The retention and attraction of talented researchers to the State is key to the sustainability and growth of its health and medical research, translation and practice. The Victorian Government, working in partnership with Universities, medical research institutes and the health care sector can assist with providing resources, infrastructure and bringing together expertise to showcase the activities available in Victoria.

In relation of attracting talent to Victoria, leading health and medical researchers and clinician-researchers are likely to be attracted to Victoria if the State has world-class infrastructure, facilities, cutting edge research programs and outstanding support. The University of Melbourne has established a number of programs to bring outstanding talent to our institution: our challenge is to provide substantial start-up support for these individuals whom generally expect that they will be able to bring or recruit a postdoctoral research team and have access to world-class facilities to continue their research. Programs such as VESKI, which provide \$50K support annually for three years, are to be commended, but could be expanded to increase the funding support available and offer greater flexibility in the recruitment and application process: the recruitment of world-leading researchers takes substantial time and must be managed carefully. Often, the University must make an offer that is outside of the timeframe of the VESKI round. The VESKI guidelines also render ineligible anyone who is domiciled in Australia at the time of application.

As well as attracting international talent, it is vital that we invest in growing and retaining Victorian talent. As discussed elsewhere in this submission, support for capacity building in the new sciences of the future, interdisciplinary research and in genomics, health informatics, biostatistics and health services research is essential. This includes from undergraduate through to postgraduate programs, but commences with primary and secondary schooling: the public needs to recognise the excellence of Victoria's contributions to scientific and medical research and its translation, in the same vein that we reward and aspire to sporting excellence. Our children need to be science, technology, engineering, mathematics and medicine literate and aspire to careers in these fields. Programs that raise awareness in these areas are of critical importance to Victoria.

The Government can thus continue and provide additional support through education and training including:

- Additional support for science-awareness programs in schools and the community;
- Top-up and full scholarships for undergraduate and postgraduate research study for Victorian students in priority areas;
- Support for specialist skills training for the current workforce as part of their continuing medical education requirements;
- Encourage international exchange programs.

Finally, the Victorian Government has the opportunity to showcase the critical mass of activities available in Victoria and to enhance those activities by supporting and expanding the role of the Academic Health Centres. Through these Centres, the State will be able to coordinate activities that are truly international and competitive.

Supporting the careers of clinician scientists

Clinical scientists face a number of pressing challenges that have enormous implications for the continued provision of quality health care at manageable cost in Victoria. Firstly the intense professional requirements for clinicians make the career path almost untenable. Extensive years of training combined with the insecurity of funding, and workload pressures in hospitals means that fewer medical professionals are able to pursue the critically important role of clinician scientist. In addition the tightened grant-funding environment means that clinical scientists struggle to gain the resources necessary for undertaking research. These issues are compounded by the long-term nature of developing clinical scientists, and as a consequence a generational approach needs to be taken to addressing issues. A multifaceted response should include funding, training, time allocation, prestige and infrastructure.

With respect to the career development of clinician scientists there is substantial scope for Academic Health Centres to be leveraged to provide a coordinated approach to career development. Further, the Victorian Government should provide incentives for health care services to encourage the engagement of their clinical staff with research and its translation; currently there are few such incentives available. Government can also assist with establishing prizes and awards that restore prestige to clinical science.

Our recommendations are:

- Providing funding support for clinical fellowships (up to five years) that enables clinical staff employed in

Victorian public hospitals to have time preserved for health and medical research. In addition, require that hospitals report on the number of clinicians engaged in research and the outcomes of research;

- Establish a new category of awards within the Victoria Prize for Science and Innovation that specifically rewards excellence in translational research in a clinical setting.

Women in health and biomedical research

Women's participation in the broader science research workforce is characterised by low levels of retention after postdoctoral appointments, where for many women, family formation and short-term contracts of employment collide to make a research career unsustainable. This is despite the large numbers of women at the PhD level in the biological sciences.

Solutions to the problem of why women find it so difficult to progress to senior academic appointments in biomedical research are complex and require a range of interventions including those to support more flexible non-traditional career paths, provide affordable and accessible childcare, and assist with career mobility. Specific State Government interventions could include grant schemes targeted to women in biomedical research, recognising career interruptions.

Consideration should be given to an award system for institutions to deliver active programs to address gaps in the promotions pipeline for women, such as the Athena Swan Charter developed by the Equality Challenge Unit in the UK to advance equality and diversity in Universities and Colleges. The Charter supports awards to institutions or departments, and provides resources on good practice to advance the careers of women in science research. Signing up to the Charter provides a demonstration effect for change at the organisational level and a recent review of the Charter found that it had made a positive impact on women's career progression at the institutional level.

The Victorian Government can also play a role in developing and supporting strategies for health and medical research workforce development that include improving the evidence base for best practice gender equity in the sector, and the monitoring and evaluation of initiatives to improve women's representations at senior levels.

7. Advancing international collaborations, industry-research engagement and innovation

Future economic growth in developed economies will depend upon entrepreneurialism that creates distinctive intellectual property, high quality research of international standing, translation of that research and support for the research and entrepreneurial talent required to direct this effort. In our experience, this will be advanced in the Australian context, through partnership between government, industry and universities.

The key challenges that Victoria faces in its start-up ecosystem are the lack of support at the early stages of the commercialisation pipeline and the need to build the base of entrepreneurial skills, in particular:

- Most of the investment that occurs at the pre-seed funding stage will never make a commercial return. But the provision of support at this early stage is absolutely critical to build the pipeline of potential businesses that can go on to bid for seed funding and venture capital. It is a classic example of market failure that requires State intervention.
- The problem most commonly encountered, when trying to commercialise researcher generated intellectual property, is that the "invention" is at such an early stage that it cannot attract the dedication of a suitably skilled, experienced entrepreneur to plan and execute its commercial trajectory. At this early stage of product development there is little value in creating spin-off companies, as substantial work is usually required to establish the prima facie case for commercialisation.
- Innovation ecosystems thrive on activity density. Every successful innovation ecosystem around the world has, at its core, at least one world-class research institution and a number of successful multinational companies operating symbiotically. In Melbourne we have world-class research institutions but we demonstrably lack engaged multinationals. Whilst this nucleus is not sufficient to generate a thriving innovation ecosystem, there can be no doubt that it is a necessary precursor that generates the environment in which start-ups and small business can also thrive.

Reframing the University of Melbourne’s approach to industry collaboration and innovation

For its part, the University is drawing on international experience to build the economic, physical, and networking assets that are essential ingredients to a successful innovation district. When these three assets combine with a supportive, risk-taking culture they create an innovation ecosystem—a synergistic relationship between people, firms and place (the physical geography of the district) that facilitates idea generation and accelerates commercialisation.

Precinct development harnesses the economies of aggregation by providing distinctive spaces for engagement, pathways for students to work with industry, researchers to engage with peers, and companies to acquire and support new ideas. For example, major initiatives such as Carlton Connect and the development of a productive partnership with IBM, has been instrumental in IBM establishing one of their Global R & D Labs near campus.

Victoria is in the early stages of building a self-sustaining innovation ecosystem, unlike say Israel, which has been investing over the last 40 years to have the developed system it has today. The Victorian Government’s policy activity recognises that we have challenges in growth, focus, scale, success, relocation and the risk of an entrepreneurial brain drain.

As part of the transformation of its approach to innovation and industry engagement, a new service stream called Research, Innovation and Commercialisation (RIC) has been established to manage all research and commercial activity for the University. This group combines what was previously known as Melbourne Research with the University’s commercial company, UoM Commercial Pty Ltd, creating a single organisation with responsibility for the administrative and commercial aspects of \$400 million of grant and commercial income. A key role is to support academics to expand commercial engagement and income.

RIC is unique in the university sector as it places senior, industry/government experienced individuals at the heart of Faculty academic and professional operations. Business Development Directors are being established in the Faculties of Medicine, Dentistry and Health Sciences, Engineering, Science, Education, Arts, Business and Economics, charged with maintaining a focus on current engagement activities, as well as growing partnerships with Industry and Government. They also serve as an outward facing point of contact with Government, Industry and the broader community to provide a consistent face to partners. They are supported by experienced staff in grants, contracts, research integrity and ethics, teaching and learning (custom programs) and major initiatives (CRCs, Centres of Excellence etc). While Business Development Directors will assess commercialisation opportunities, the University is limited in its capacity to fund the very early stage work required to generate starting value propositions.

Need for a Proof of Concept Fund

The Melbourne Accelerator Program⁷ at the University of Melbourne has proven to be a successful model to nurture start-up businesses. Teams of potential start-ups from across the University of Melbourne work through a structured program to develop and grow their business, with top startups awarded access into the Startup Accelerator receiving \$20,000 funding, office space, structured mentoring and networking opportunities. However, at the end of this development year, the teams still require more support and development before the idea is ready for seed funding.

This gap can be bridged by a “proof of commercial concept” fund. It fills the gap between a \$20,000 grant under a MAP-styled accelerator program and a Uniseed or Medical Research Commercialisation Fund that undertakes investments starting at \$250,000. We argue that for every major commercialisation success that reaches seed funding stage, there are at least 10 would-be successful ideas that never make it because of the gap in funding at the pre-seed funding stage. It is an example of market failure that exists at the early stage of the transition of technological breakthrough to a commercial product.

The model for a Proof of Concept (PoC) fund is currently under investigation by the University of Melbourne in a number of contexts. The objective is to create a strong pipeline of proposals further along the value chain to the point where it becomes clearer whether or not there will be scope to secure seed funding towards a pathway of a licence, spin-out company, IP sale etc. Two funds are envisaged— one for the physical sciences and one for life sciences. These mechanisms will bring together the two established ingredients of human and financial capital and fill a long-standing gap in the research translation continuum.

The University of Melbourne is keen to partner with other key research institutions in order to build critical mass and ensure that this mechanism becomes an established piece of vital innovation infrastructure for Victoria. It is currently contemplated that the University of Melbourne (and select partners) will be responsible for raising the requisite capital. **The opportunity for Government is to facilitate this PoC activity by funding operational costs.** This funding will ensure that we can retain the best talent to manage the fund and so systematically generate high value jobs and export income for Victoria.

⁷ <http://themap.co/>

The PoC fund would provide grants of between \$50,000 – \$200,000 over 12 months for eligible activities that include: prototype development and / or validation; technology scale up and / or validation studies; in vivo proof of concept studies in relevant disease models for therapeutic opportunities; software coding and documentation to enable field trials; and external advice on IP, market, business planning, technical and/or competitive analysis to support the commercial potential of the opportunity.

From a State Government perspective this represents a low-risk, high-return investment in human capital infrastructure, which is vital in our quest to see more effective research translation and innovation outcomes.

New models for pharmaceutical drug development

In the last decade, the R&D arms of international Pharma have increased their focus on development and withdrawn to some degree from conducting their own research. This shift stimulates the development of novel models of drug discovery where academia undertakes the innovative ‘front end’ aspects of the drug discovery value chain, especially clinically- / patient needs-driven projects.

The State is well positioned to harness the world-class research undertaken within Victoria to bridge the translational gap between basic discovery research and late stage drug development undertaken by pharmaceutical companies. The University of Melbourne is working on plans to better integrate its biomedical and health research platforms, preclinical and translational research and clinical trial capabilities to attract international Biotech and Big Pharma to the Melbourne Biomedical Precinct. In this regard, the University of Melbourne is in confidential discussions with the State Government to identify how we might work together to achieve this outcome.

Internationalisation of health and medical research

As Australia’s leading University, the University of Melbourne has an international outlook in both its research and education. In 2015, 41% of the University’s commencing graduate research student cohorts (Masters Research, PhD) degree programs were international. Within the Faculty of Medicine, Dentistry and Health Sciences, 19% of the current graduate research student cohort is from Asia.

The University has a strong and rapidly developing engagement with China, as exemplified by two world-leading collaborations, both established in 2014:

- **Sino-Australia Joint Laboratory for Emerging and Re-emerging Infectious Disease Research:** a collaboration between the Shanghai Public Health Clinical Center, Fudan University and the Doherty Institute at the University of Melbourne. The Joint Laboratory will serve as a platform for collaborative studies between infection and immunity researchers from the two institutions to examine human immune responses to avian-origin influenza. To date, this work has resulted in publications in prestigious journals including Nature Communications and the Proceedings of the National Academy of Sciences of the United States of America.⁸
- **Joint Center for Psychiatry Research and Training:** a collaboration between the Asia Australia Mental Health (a consortium of the Department of Psychiatry at the University of Melbourne, Asialink and St Vincent’s Mental Health) and the Health Science Center, Institute of Mental Health at Peking University (PKU). The Center will jointly train PhD students enrolled at either UoM or PKU. Since its establishment, the Center has conducted various training and research in the mental health field. The Center’s activities have also been extended to Guangzhou City, Shenzhen City and Shantou City in Guangdong Province to further develop the Center’s psychiatric research and training.

The internationalisation of research by the University of Melbourne is also reflected in the quality and quantity of our research publication output. Between 2010-2015, from its 21,150 peer reviewed publications in the subject area “Medical and Health Sciences”,⁹ University researchers collaborated with co-authors from 156 countries, of which Australian co-authors were represented in 88% of publications. Co-authors from Singapore (3.4% co-authors), China (2%) and Japan (2%) ranked in the top 20 collaborating international countries with the University of Melbourne. Further, the quality of papers (measured by citation impact) increased between 2.3 and 4.2 times the University’s average citation impact when co-authors from these countries were included on publications. We expect that there will be substantial growth in quality publications with our Asian colleagues over the next decade.

⁸ Wang et al (2015) Nature Communications. Vol 6. 13 May 2015
<http://www.nature.com/ncomms/2015/150513/ncomms7833/abs/ncomms7833.html>; Wang et al (2014) Proceedings of the National Academy of Science. 111(2): 769-774 www.pnas.org/cgi/doi/10.1073/pnas.1321748111

⁹ InCites dataset updated Aug 14, 2015. Includes Web of Science™ content indexed through May 29, 2015.

There is able scope for the Victorian Government to provide leadership in the internationalisation of health and medical research. As well as enhancing research and translation capability, an internationally-focussed outlook, especially to Asia, has the potential to develop new markets for export of Victorian health services and also grow the State's international education market, where research excellence and reputation is a primary driver for student recruitment.

We are of the view that there is significant scope to leverage Victoria's bilateral trade links with China, India and Indonesia. There is potential for joint funded research programs such as those offered by NHMRC's bilateral programs with the Indian Council of Medical Research or the National Natural Science Foundation of China. The University has undertaken extensive groundwork in developing the research and cultural relationships with the most prestigious research and higher education institutions in India and China that will ensure that such programs reach their potential.

Further, in relation to the Victorian Government supporting access to the health and medical research sector to access international funding, the development of 'tripartite' investments with established organisations such as Wellcome Trust, Victorian researchers, and Asian regional researchers can build collaborative links between all parties. This will build capacity of regional based researchers, increase the number of "Asia ready" researchers and institutes in Melbourne and Victoria, and profile Melbourne as an international health and medical research hub.

Such investments have the potential to make the greatest impact when they are innovation orientated and geared to existing global clinical and medical needs. If co-funding were available from the Victorian Government, this should be targeted to priority international and industry partnerships and Victorian health priorities, and provide funding for research and collaboration that cannot otherwise be accessed.

In particular, funding should be available where existing national schemes do not cover specific program calls, or may not be considered sufficient to support the full cost of participation. For example the NHMRC-EU program provides some funding to link to European innovation programs. This is limited to \$500,000 for specific calls selected by NHMRC. The H2020 program is the world's largest innovation program and is highly competitive. Fostering participation by Victorian researchers in these research/industry consortia has clear potential to build, strengthen and leverage partnerships with European research, institutions and industry partners that are focused on delivery of innovations that address existing societal needs.

8. Securing development and commercialisation opportunities

The University of Melbourne has addressed the substantive issues around securing development and commercialisation opportunities in Section 7. We also add the following observations:

- We support the development of a health and medical research Innovation Hub for the State, which has a strong focus on commercial development. As discussed in Section 6, commercialisation and effective translation of the State's research is part of a vibrant ecosystem.
- In order to develop this ecosystem further, our homegrown companies, such as CSL, Cochlear, Universal Biosensors and others must be supported and encouraged to invest in Victoria's outstanding research capability. Much of the State's recent industry engagement strategies are primarily focussed on SMEs, and while this is to be commended, many SMEs do not have the technical or financial capacity to engage. Engagement with both SMEs and larger companies should be supported. Further, it is vital that we attract multinational corporations in priority areas to locate R&D centres within the State and provide incentives for them to collaborate with local researchers. For example, the location by Johnson & Johnson to Melbourne would be of critical importance to the development of the State's MedTech industry.
- It is important that the State's initiatives are also aligned with Australian Government initiatives, for example, Industry Growth Centres.
- In terms of encouraging the next generation of Victorian innovators, programs such as the University of Melbourne's Melbourne Accelerator Program (see Section 6) provide an example of what can be achieved.
- The University is currently developing a postgraduate course in BioDesign Innovation, modelled on the Stanford University BioDesign course and the Hebrew University of Jerusalem.¹⁰ Over one academic year, teams of students selected for the course will receive instruction in innovation and entrepreneurship and complete a significant project for which they will receive course credit. The teams will develop new, valuable knowledge, enhance their problem solving and concept formulation skills, learn how to work effectively in multidisciplinary teams, and receive training in the design and start-up process. The rich experience will equip graduates of the Program to understand and become involved in innovation and entrepreneurial activities throughout their professional careers.

¹⁰ <https://www.afhu.org/biodesign-medical-innovation-program/#.VegOmGMXKPo>

9. Optimising funding models and sources

The health and medical research funding landscape is complex. Support for research is received through the NHMRC, various programs of State and national governments, industry, the philanthropic sector and the public. By far, NHMRC funding provides the majority of funding support that underpins fundamental health and medical research. Within Victoria, the sector receives ~42% of NHMRC funding. Little support is available from the Australian Research Council which has narrowed its eligibility criteria by explicitly not funding health and medical research or research with potential health application in the last few years.

The challenge for Victorian researchers is that Victoria is probably at the ceiling for NHMRC funding with the capacity to increase the overall funding proportion, relative to the national allocation, limited. Consequently, many meritorious projects are not funded. Further, the new Medical Research Future Fund will not ramp up to full capacity for a few years. We have also seen significant investments and future positioning by other Australian states in science, technology, engineering and medicine particularly New South Wales and Queensland. However, these investments are dwarfed by those made by Singapore, which has committed S\$16.1 billion over 2011-2015 in R&D – 20% more than the previous R&D budget.¹¹

The University of Melbourne considers that there is a role for the State to play in funding strategic investments in health and medical research and capacity building measures that improve health outcomes for Victorians. The recent \$25 million investment in the Melbourne Genomics Health Alliance is an excellent example which demonstrates the State's international leadership, as is the support provided for game-changing initiatives such as the Melbourne Brain Centre, the VCCC, the Peter Doherty Institute and the Aikenhead Centre for Medical Discovery.

We have also suggested in this submission a number of other areas suitable for strategic, financial investment by the State, namely:

- Support for coordination and collaboration across the Melbourne and Monash Academic Health Science Centres (Section 2);
- Capability development (skills, career paths and critical mass) for health services and health economics research and translation (Section 2);
- Investment in developing critical mass in convergence science and biomedical engineering and support for convergence science projects that fall into the ARC/ NHMRC funding crevice (Section 3);
- Investment in health informatics, bioinformatics, biostatistics and data science capability (Sections 4, 5);
- Ongoing development in linking and integrating platforms such as GRHANITE and BioGRID (Section 4);
- Attracting talented researchers and clinician-researchers back to Australia through ongoing and expanded support for VESKI (Sections 4, 6);
- Investment in scholarships, fellowships and international exchange programs for the HMR workforce (Section 6);
- Establishment of a Proof of Concept Fund (Section 7);
- New models of pharmaceutical drug development (Section 7);
- Bilateral and trilateral co-investments in priority areas with international collaborators (Section 7).

The University notes the consultation question by the State about how siloed funding mechanisms can be changed to facilitate greater collaboration. These funding mechanisms are a function of the policy directions to ensure that the allocation of research funding is made transparently via a national competitive process (supporting excellence), while also enabling all eligible Australian institutions to participate (supporting egalitarianism). The grant review mechanism also provides the opportunity for national and international peers to critique and provide feedback on the research ideas and methodologies within applications.

Whilst the University supports this national competitive process, it requires substantial time and effort on the part of our researchers to participate. There is an inherent bias against high-risk projects where scientific concepts are untested and lesser funding for research that is on the path to translation and commercialisation. Further, changes to funding rules, especially from the Australian Research Council, have reduced incentives for collaboration: researchers can be named on fewer grants so researchers are less likely to participate on other grants where they might have had a research mentorship role.

¹¹ <http://www.nrf.gov.sg/research/r-d-ecosystem/overview>

Notwithstanding these challenges, strong collaboration remains across the sector, particularly based on geography. Many of the University's leading researchers are actively engaged in clinical care and research and education. They hold joint appointments, or work closely with the State's leading hospitals and health care providers and medical research institutes. Both the Melbourne Brain Centre and the Peter Doherty Institute for Infection and Immunity are brilliant examples of this, while the VCCC will be a similar enabler in cancer research and care.

The University has established additional mechanisms that aim to facilitate collaboration across the health, science, technology and innovation ecosystem. Many of these are initiatives based on a 'virtual institute model' so that our researchers remain embedded in their home disciplines but also collaborate across disciplines. As discussed in Section 3, the University is currently establishing the Graeme Clark Institute for Biomedical Engineering and Innovation which will operate in a similar virtual model but with enablers and incentives that encourage trans-disciplinary collaboration with applied and strategic R&D and innovation projects driven by health and industry needs.

Indirect costs of research

It is stated within the Discussion Paper (page 20) that *'Private and public hospital researchers are unable to access indirect cost funding through any of the above schemes. Accordingly this presents a marked disincentive for hospital management to allocate time for clinical staff to also undertaken research'*.

The University of Melbourne considers that this statement is not wholly correct. It is correct to state that it is a challenge for clinicians and other health professionals to find the time and resources to directly undertake research, given their workloads, but we do not consider that this is a function of lack of access to funding for indirect costs. As much as anything, it is access to direct costs for research that will support the buyout and backfilling of clinicians and health professionals' time that is required. In summary, the University considers that this is a complex issue that is at least in part a matter of incentives and direct funding and which requires further investigation to understand and resolve.

One area where the State can provide leadership by example is in funding the full costs of research (staff time plus project costs plus indirect costs) on contracted research activities.

Philanthropic sector engagement

Philanthropic funding makes a substantial, essential and highly-valued contribution to health and medical research in Australia. There is substantial awareness amongst sophisticated donors of the importance of the philanthropic sector to HMR. Nevertheless, there is scope for the State to provide incentives for philanthropic support of HMR, for example:

- Co-funding of philanthropic Chairs or senior positions, to bring the endowment value to a sustainable level. These could be in areas of specific interest to the State, e.g. health services, cancer.
- Organise a conference to bring leading philanthropists together in Victoria, with universities and medical research institutes to discuss how to best promote a culture of giving in Victoria.
- Provide co-investment incentives for HMR areas that receive less philanthropic support.

Attachment One: Achievements in health and medical research and translation by University of Melbourne researchers

Epilepsy: Research and clinical translation in the field of epilepsy at the University of Melbourne, Royal Melbourne Hospital, Austin Hospital, St Vincent's Hospital and the Royal Children's Hospital has contributed substantially to major neurobiological advances in the diagnosis and treatment of human epilepsy over the last 10-15 years, driven by major discoveries in genetics, imaging and neural engineering. Key outcomes include:

- Transformation of clinical epilepsy practice from diagnosis to treatment: Professors Sam Berkovic and Ingrid Scheffer¹² have discovered ~50% of the known epilepsy genes. They have changed clinical practice by enabling a swift and definitive diagnosis based on genetic testing rather than a “descriptive” diagnostic label for certain patient groups, thus providing guidance for selecting the most effective anticonvulsants, and informing prognostic and genetic counseling.
- Innovative therapeutic approaches are leading to new clinical and diagnostic approaches with high commercialisation potential. Professor Mark Cook has led the first “in man” trial of an implantable seizure prediction device which demonstrated that intracranial EEG monitoring is feasible in ambulatory patients with drug-resistant epilepsy. Long term, this will improve understanding of seizure generation and result in the development of new management strategies.

Reform in mental health care for adolescents and emerging adults: A comprehensive program in youth mental health, led by Professor Patrick McGorry¹³, has developed innovative, cost-effective treatments and systems of care. This includes the national *headspace* program (\$54M government funding) and early intervention treatments to address the needs of young people with a range of emerging mental disorders. These programs serve as the model upon which hundreds of early intervention and youth mental health services in the world are now based.

New vaccines to improve child health: In 1973, Professors Ruth Bishop and Ian Holmes discovered rotavirus, a leading cause of child death. The MHP rotavirus vaccine development team in Parkville has recently developed the RV3-BB vaccine, which, unlike current vaccines, can be administered at birth. It is currently in Phase III efficacy trials in Indonesia, funded by the Gates Foundation.

Understanding the immune response: The work of Professors at The Peter Doherty Institute for Infection and Immunity¹⁴ and has revolutionised our knowledge of the immune system. This work has redefined the role of the T-cell in immunity with profound consequences for the management of cancer and understanding of inflammatory conditions.

Tailored prevention in high risk populations and their families: Cancer registries developed by UoM researchers, Professors John Hopper, Mark Jenkins and Melissa Southey, have facilitated new cancer risk models, penetrance studies of known genes and the discovery of new susceptibility genes in cancer. These large-scale studies in breast and colorectal cancer have enabled the integration of new genetic information into clinical genetics practice to improve tailored prevention, screening strategies and treatment options for individuals/ families at high genetic risk of cancer.

Specialist Adolescent Care: The RCH Centre for Adolescent Health (CAH), led by Professors Susan Sawyer and George Patton has paved the way in developing clinical, service system and preventive programs providing support for ~5000 youth per year in areas such as self-harm prevention, eating disorders, high risk behaviours, adolescent pregnancy, chronic illness and gender dysphoria. These programs have been underpinned by major population-based longitudinal studies and prevention trials. Patton is currently leading the Lancet Commission on Adolescent Health and Wellbeing.

Population Health and Wellbeing: The Melbourne School of Population and Global Health's Centre for Health Equity, directed by Professor Brian Oldenburg, undertakes research that strongly emphasises “making a real difference” to the health of people in Australia and other countries in our region of the world. Priority areas are in improving indigenous health, the liveability of people's living environments, the lives of children and their families and the health and wellbeing of people with heart disease, diabetes and other chronic conditions in our region.

Leadership in Intensive Care: Professor Rinaldo Bellomo, Director of Intensive Care Research at Austin Health, has led best practice in his field internationally in several areas. Two high-impact examples are the optimal use of resuscitation and metabolic support methods for critically ill patients in hospitals, and the implementation of Medical Response Units (MRU) worldwide. The MRU model is aimed at detecting and remediating the deteriorating patient in hospital settings, outside the Intensive Care Unit, before it is too late to prevent a fatal outcome.

¹² Joint winners of the 2014 Prime Minister's Prize for Science.

¹³ Australian of the Year 2010.

¹⁴ 1996 Nobel Prize in Physiology.