Victorian health and medical research strategy

Discussion paper
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The Victorian Government understands the critical role that health and medical research plays in improving Victoria’s healthcare delivery and health outcomes, in enhancing the Victorian innovation sector and in growing the economy.

This Government is committed to engaging with the health and medical research sector to identify the key priority areas that will inform the development of a Victorian health and medical research strategy. The vision for the Victorian health and medical research strategy is to optimise wellbeing and improve the health outcomes of Victorians. The objective is to embed health and medical research into the Victorian health system with the view of accelerating translation research into the clinic and community. A well-informed strategy will build on Victoria’s strengths in health and medical research, and ensure that the state’s pre-eminence in this area is not only sustained but further developed to its full potential.

As part of a consultation process, this discussion paper seeks feedback from the health and medical research sector. The key themes in the discussion paper emerged from a roundtable discussion that was led by the Hon. Jill Hennessy MP, Minister for Health, and Mr Frank McGuire MP, Parliamentary Secretary for Medical Research, on 16 June 2015.

The key themes are:
- integrating research, education and healthcare
- developing a convergence science capability
- optimising big data and informatics
- implementing a world-leading clinical trials system
- developing the next generation health and medical research workforce
- advancing international collaborations, industry–research engagement and innovation
- securing development and commercialisation opportunities
- optimising funding models and sources.

The health and medical research sector is invited to respond to the paper and to a set of questions related to each of the themes. This paper complements the Victorian Government discussion paper on Victoria’s future industries: Medical technologies and pharmaceuticals.

The responses from the sector will guide the development of the Victorian health and medical research strategy. There is now an opportunity to develop a forward-looking approach that will ensure Victoria is investing in areas that support better health outcomes and deliver societal and economic benefits. The consideration of such an approach is long overdue. The establishment of the Commonwealth Government’s Medical Research Future Fund and the significant health and wealth creation opportunities that Victoria stands to glean from this underscore the importance of adopting a strategic approach.
Purpose

The purpose of this discussion paper is to elicit stakeholders’ input into the development of the Victorian health and medical research strategy.

The discussion paper is informed by preliminary consultations with the health and medical research sector and the representative stakeholder roundtable that was led by the Hon. Jill Hennessy MP, Minister for Health, and Mr Frank McGuire MP, Parliamentary Secretary for Medical Research, on 16 June 2015. The consultations and roundtable were attended by representatives from public and private hospitals, medical research institutes, universities, Victorian statutory agencies, other key industry informants and multiple funding groups.

The critical themes that emerged from the roundtable and discussions with stakeholders have informed the key topics and initial content of this discussion paper. In addition the 2013 Strategic Review of Health and Medical Research ('the McKeon Review')1 has provided an important point of reference to inform the Victorian health and medical research strategy.

Stakeholders are invited to provide feedback by addressing the content and questions posed in this discussion paper. A list of the questions can be found at the end of each section and in Part 3. In addition, stakeholders are invited to detail five to 10 health and medical research-related actions that they consider to be critical to strengthening the sector and improving the health and wellbeing of Victorians.

Dateline for submissions: 5 p.m. (AEST)
Monday 31 August 2015.

Submissions are to be emailed to <laura.ward@dhhs.vic.gov.au>.

Submissions made after this date may not be considered. Please note that your submission may be made public. Please expressly state in your submission if you wish for it to remain confidential.

Submissions should be provided in a Word document. Responses to any one question should not exceed one page. Where you have included data or cited papers or research in your submission, please provide a reference to the source of this information.

If you would like to provide a submission but are not able to do this in a written format, please contact Laura Ward on the details below to discuss an alternative format.

Contact

Laura Ward
Manager – Health and Medical Research Innovation Hub and Health System Improvement Department of Health & Human Services
Telephone: (03) 9096 5340
Email: laura.ward@dhhs.vic.gov.au

In addition to this discussion paper, the Victorian Department of Economic Development, Jobs, Transport and Resources has made available a discussion paper Victoria’s future industries: Medical technologies and pharmaceuticals to help inform the development of an industry strategy for the medtech and pharmaceuticals sector. Submissions to this discussion paper can be made via <www.business.vic.gov.au/futureindustries>.
Scope

The scope of the Victorian health and medical research strategy encompasses the following activities that involve universities, medical research institutes and health service providers:

- **Basic research (also known as discovery research or fundamental research):** This refers to the laboratory investigations of biological processes that increase the understanding of the causes of diseases. Experiments are performed on materials derived from animal and human tissues and/or in whole animals.

- **Translation research:** This is a general term encompassing research that focuses on clinical outcomes and quality research principles, carried out by multi- and inter-disciplinary teams that explicitly address how knowledge created from the research will be used to drive advances in an area of patient clinical need.²

- **Clinical research:** This is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects.³ Clinical research includes the following.
  - **Patient-oriented research:** This type of research involves a particular person or group of people, or uses materials from humans and can include: (1) mechanisms of human disease; (2) therapeutic interventions; (3) clinical trials; and (4) the development of new technologies.
  - **Epidemiological and behavioural studies:** These examine the distribution of disease, the factors that affect health and how people make health-related decisions.
  - **Outcomes and health services research:** These seek to identify the most effective and most efficient interventions, treatments and services.³

The critically important and related population health and illness prevention research will be developed as part of the Victorian Health and Wellbeing Plan 2015.

Engagement with the biotechnology, medical technology, pharmaceutical, investment and philanthropic sectors will be included as a strategic approach to building an innovative health system in Victoria.
Victoria has a world-leading health system that is underpinned by internationally recognised excellence in medical and clinical research, medical and biosciences education and healthcare innovation. Victoria’s strong foundation in health and medical research has produced globally recognised biomedical researchers. A number have gone on to win prestigious international awards including the Nobel Prize and Lasker Award.

Victoria’s leadership in medical research within Australia is undisputable, with the state consistently attracting more than 40 per cent of funding from the National Health and Medical Research Council (NHMRC) (Figure 1). Victoria’s health and medical research sector also attracts substantial funding from the Australia Research Council (ARC) and the Commonwealth-funded Cooperative Research Centres (CRC) program.

Victoria’s health and medical research sector provides a strong foundation for vibrant biotechnology, medical technology and pharmaceutical sectors. Collectively, these sectors employ more than 20,000 people.

The Victorian Government continues to invest in the state’s health system by supporting: health services in metropolitan, rural and regional areas; medical research institutes; universities; community groups; not-for-profit organisations; and the commercial sector. The state has committed to building a world-class health and medical research workforce and has made significant investment in research infrastructure such as the Australian Synchrotron, the Victorian Life Sciences Computation Initiative and the Victorian Cancer Biobank. In addition, the state continues to fund clinical registries and electronic health record systems across public health services, thereby enabling healthcare professionals to better capture data and information for improved patient management.

Victoria’s health and medical research excellence in discovery and translation research continues to deliver significant benefits to the state, the nation and the international community. Research innovations have made a real impact on people’s lives by delivering new treatments (for example, immuno-therapeutics), diagnostics (for example, point-of-care diagnostics) and medical devices (for example, bionic implants). Innovation in public health research has also led to effective programs in disease prevention.

### Figure 1: NHMRC funding by state, 2010–2014

Source: NHMRC 2015

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The challenges of healthcare delivery

Healthcare in Victoria and around the world is evolving rapidly. The challenges associated with an ageing population and increasing incidence of chronic disease necessitates a more focused approach to health and medical research. Indeed, the ratio of health expenditure to gross domestic product (GDP) has increased from 6.8 per cent in 1986–87 to 9.5 per cent in 2011–12. Total health expenditure has grown in real terms at an average rate of 5.4 per cent per year over the past decade, while GDP has grown at a slower rate of 3.1 per cent per year.\(^5\)

There is recognition that Australia is facing a growing burden of lifestyle-related chronic diseases that are placing significant demands on the health system. Preventing chronic diseases and keeping people healthy and out of hospital have become increasingly important issues for governments, communities and healthcare professionals to address.

The National Priority Health Areas draw attention to the challenges faced by the health system as the clinical conditions listed collectively contribute to almost three quarters of the total burden of disease of Australians:

1. Arthritis and musculoskeletal conditions
2. Asthma
3. Cancer control
4. Cardiovascular health and stroke
5. Dementia
6. Diabetes mellitus
7. Injury prevention and control
8. Mental health

In the area of health, the importance of developing treatments, solutions and preventive strategies to improve physical and mental wellbeing at the individual and population levels was emphasised. Further, the steady increase in health expenditure over the previous two decades necessitates increased health system efficiency and a reduction in unnecessary healthcare interventions. There is also a need to generate increased economic returns by fostering partnerships with industry and improving knowledge translation and commercialisation of Australian discoveries.

Accordingly, the following priority areas for health and medical research were recommended by the Commonwealth Government:

1. Better models of healthcare and services that improve outcomes, reduce disparities for disadvantaged and vulnerable groups, increase efficiency and provide greater value for given expenditure.
2. Improved prediction, identification, tracking, prevention and management of emerging local and regional health threats.
3. Better health outcomes for Indigenous people, with strategies for both urban and regional communities.
4. Effective technologies for individuals to manage their own healthcare, for example, using mobile apps, remote monitoring and online access to therapies.
Investment in health and medical research in Australia delivers high returns to the population through improved longevity and health outcomes. Additionally, health and medical research delivers a return on investment of around 117 per cent. This equates to a dollar invested in Australian medical research and development returning an average health benefit of $2.17.8

The Victorian Government is committed to investing in the state’s excellence in health and medical research by:

- supporting world-class medical research and by providing increased funding and resources to Victoria’s leading research institutions
- encouraging and supporting cross-collaboration between medical researchers, both domestically and internationally
- exploring models of translational clinical practice
- improving the availability of and access to high-quality research and data.

The key election commitments listed above are supported by the following funding commitments:

- $25 million over four years for the application of genomics in healthcare
- $200 million for the Future Industries Fund to support six high-growth sectors that include medical technology and pharmaceuticals
- $60 million for the Aikenhead Centre for Medical Discovery (contingent on matched funds from the Commonwealth Government)
- $150 million to build Australia’s first stand-alone cardiac hospital, the Victorian Heart Hospital, which will also house the Monash Cardiovascular Research Centre
- $60 million to transform Orygen Youth Health’s Parkville facility, the world’s largest international research institute for youth mental health
- four reverse international trade missions with a focus on health and medical research.

Ongoing commitment from the Victorian Government will foster expertise and strengthen the capability and capacity of the sector. This will maximise the potential of health and medical research to alleviate the burden of diseases, improve health outcomes and deliver societal and economic benefits for Victorians (Figure 2).
Part 2: Strategic directions and themes

The vision for the Victorian health and medical research strategy is to optimise wellbeing and improve the health outcomes of Victorians. The objective of the strategy is to embed health and medical research into the Victorian health system with the view of accelerating translation research into clinics and the community.

The World Health Organization defines a health system as ‘consisting of all organisations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities’. Within the Victorian context, the health system comprises the public and private system that includes consumers, patients, carers, policymakers, academics, healthcare professionals, healthcare and aged care agencies, governments, insurers, medical technology companies, biotechnology companies, pharmaceutical companies and information and communications technology (ICT) companies.

Against this landscape is an evolving health system that is moving towards a patient-centred model. This model is a paradigm shift from the traditional approach of clinician-driven care. Expanding a patient-centred care model across the health system is a challenge because of the diversity and interrelatedness of the components within the system. An additional complexity is that different disease areas have different processes of clinical practice, so there cannot be a single patient-centric approach.

Adding to these challenges is the growing importance of precision medicine (also known as ‘personalised medicine’), a patient-centred paradigm that shifts traditional medicine away from a one-size-fits-all approach to clinical practice. The shift from a tradition model of medicine that is reactive to a more proactive approach has the potential to:

- deliver new diagnostic tools and applications that better predict disease progression
- make better-informed clinical decisions with better use of data and information.

The United States and the European Union have made a significant investment into funding research into precision medicine because of its potential to transform society and the economy through improved health and wellbeing. Not only is precision medicine changing funding models, it is also changing research models as technological advancements and emerging disciplines such as biomedical engineering (for example, tissue engineering, nano-engineering, robotics and computational engineering) contribute to innovative solutions for the medical technology, biotechnology and pharmaceutical sectors.

In addition, precision medicine is hailed as a disruptive innovation on traditional business models, with new entrants from direct-to-consumer markets and low-to-high-end technology providers. Alliances with non-traditional market players are being formed as biotechnology, pharmaceutical and medical technology companies explore new ways to capture the growing precision medicine market. As an example, in 2015 Johnson and Johnson’s subsidiary company Ethicon formed a strategic alliance with Google to build a robotic-assisted surgical program.

For Victoria, the new era in precision medicine presents an exciting opportunity to build on a stronger foundation in health and medical research and to strengthen collaborations and engagement with hospitals, industry, the investment sector and the philanthropic community. The Victorian Government has initiated a process of streamlining the activities in the health and medical research sector with health services, medical research institutes and industry. This approach will lead to greater alignment of strategic directions between health and
medical research, and health services delivery programs. It should also lead to more strategic engagement of medical research institutes and universities with hospitals to drive outcomes-driven research. The medical technology, biotechnology and pharmaceutical sectors would also benefit, as they would be better informed of the unmet needs of an evolving health system. This, in turn, will lead to industry demand-driven research with greater potential to develop marketable solutions that benefit the public.

The Victorian Government recognises that progress in health and medical research is hampered by the classical ‘twin valleys of death’ in translation research (Figure 3). This metaphor is used to highlight the roadblocks that stall discovery research from being developed into clinical applications that benefit patients and consumers. The first valley (T1) of moving from bench to bedside represents promising discoveries in the laboratory requiring funding to further validate potential therapy or devices in the laboratory or animal studies. Attracting funding from investors and the commercial sector is difficult because of the early stage of the research and the high-risk nature of the projects. The second valley of death (T2) is in the early-phase (phase I and II) of clinical studies where the therapy or device has been shown to have potential; however, further funding is required to meet safety and efficacy requirements. These early-phase trials are high risk and costly for investors and commercial companies to fund. Successful outcomes from these studies would generate investor and commercial support for progression to late-stage phase II and III clinical trials.

From a health policy perspective, a third valley (T3) exists as policy and practice changes based on findings from health services research and epidemiological studies are challenging to implement and adopt at a system-wide level. A fourth valley (T4) to cross will be meeting the promise of precision medicine in delivering the right treatment to the right patient at the right time. Ongoing population-based studies will be essential to evaluating the safety, effectiveness and efficacy of such an approach. This, in turn, will inform further discovery, translation and clinical research.

![Figure 3: Health and medical research pathway from bench-to-bedside to practice](image)

As shown in Figure 4, applying a patient-centred approach in Victoria with a focus on precision medicine will remain challenging because of the interplay between the different groups that contribute data and information from diverse sources, be they from research (for example, genomics and other ‘omics) and/or clinical or industry environments. In precision medicine, a strategic approach is essential in integrating the different data types spanning DNA, RNA, protein, cellular pathways, cellular networks, tissues, organs, individuals and the wider population to improve the understanding and management of diseases.

As the Australian Institute of Health and Welfare highlighted, ‘the health of the nation depends on our health as individuals and vice versa. A “healthy” health system, therefore, is fundamental to our national– and personal – wellbeing and prosperity.’

The following themes in this section will be explored further to identify opportunities and challenges faced by the Victorian health and medical research community:

- integrating research, education and healthcare
- developing a convergence science capability
- optimising big data and informatics
- implementing a world-leading clinical trials system
- developing the next generation health and medical research workforce
- advancing international collaborations, industry–research engagement and innovation
- securing development and commercialisation opportunities
- optimising funding models and sources.

Questions

1. What are the areas of greatest strength in translation research that Victoria could build on and what criteria should be used to determine this?

2. How can these strengths be enhanced to ensure Victoria has the critical mass and scale to be globally competitive or what strengths does Victoria need to develop?

3. What are the five priority areas of focus for health and medical research in Victoria over the next five years based on Victoria’s strengths and needs?
Figure 4: The health and medical research ecosystem leading to improved health outcomes

DHHS = Victorian Department of Health and Human Services;
MRIs = medical research institutes

Source of images: US Department of Energy Genomic Science program 2015
Integrating research, education and healthcare

Academic health science centres

In recent years, there have been a number of Australian articles highlighting the importance of integrating research, education and healthcare through academic health science centres (AHSC).1,16-18

“AHSC is where a leading university joins with a major tertiary healthcare provider in a tripartite mission of excellence in clinical service, research and education.”16

AHSCs or equivalent models in the United States, Canada, United Kingdom, Europe and Asia have been established to advance research translation and improve health outcomes through evidence-based practice.

In recognising the importance of AHSCs, the Victorian Government has supported the establishment of the following geographically based centres:

• Melbourne Academic Health Science Centre
• Monash Partners Academic Health Science Centre
• Western Alliance Academic Health Science Centre.

This collaborative translational research model is supported by the NHMRC, with the announcement in March 2015 of four NHMRC Advanced Health Research and Translation Centres following assessment by an international panel of experts.19 Of the four centres, two are based in Victoria:

• Alfred Health and Monash Health and Partners Advanced Health Research and Translation Centre
• Melbourne Health Care Partners Advanced Health Research and Translation Centre.

A challenge for the Victorian AHSCs is to develop a common vision that promotes the sharing of resources, capability and expertise for improving the effectiveness, efficiency, safety, and quality of healthcare in Victoria. The success of AHSCs will be made evident in health services research studies that identify effective policy and practice changes that lead to improved health outcomes.

Health services research

The importance of health services research is exemplified by the dual need to stem rising healthcare costs and improve health service delivery. Such research is an essential component to achieving these goals in areas where commercial drivers are lacking.

Health services research encompasses a range of activities such as evaluation of the quality, safety and cost of healthcare, assessment of healthcare needs, measurement of health outcomes, evaluation of healthcare improvements and review of the allocation of healthcare resources. It applies an interdisciplinary approach by drawing expertise from disciplines such as biostatistics and mathematical modelling, nursing, economics, political science, epidemiology, public health, medicine, engineering, pharmacy and psychology.20

As it is an emerging field in Australia, skill shortages exist, and building critical mass of researchers will take some time. Also of importance is investment in:

• developing more applied research capacity
• the capability to implement change and scale up
• infrastructure for data collection and data linkage
• improving the quality of data and timeliness in accessing data
• processes for accessing and sharing publicly funded datasets
• analytics to make sense of the data.

Questions

4. How can the performance of Victorian academic health sciences centres be optimised to advance research, education and healthcare?

5. What are the top areas of priority for health services research in Victoria?

6. What are the skills shortages and other current deficits in health services research? How can Victoria address these shortages/deficits?

7. What are the barriers to translating health services research into practice and policy? How can these barriers be overcome?
Developing a convergence science capability

**Precision medicine**

Precision or personalised medicine is an emerging practice of medicine due to scientific progress arising from the Human Genome Project and a deeper understanding of the molecular mechanisms of disease. In precision medicine, the patient-specific clinical and molecular information is used to diagnose and categorise disease and to tailor the best clinical treatment for improved clinical outcomes.

Precision medicine is breaking down traditional silos of discipline-based research. Increasingly, medical research is being aided by engineers, computer scientists, physicists, mathematicians and statisticians in a new discipline of convergence science. In a seminal paper from the Massachusetts Institute of Technology, convergence science is hailed as the ‘third revolution’ in biomedicine (after molecular and cell biology, and genomics).

While convergence science has gained prominence through genomics (and other ‘omics’ research, emerging disciplines such as health services research and biomedical engineering are increasingly reliant on the growing merger of biosciences, physical sciences, engineering, computer science, mathematics and beyond to drive research innovation. Convergence scientists are a new class of researcher with the versatility to cross discipline-based language and conceptual barriers.

The United States, the United Kingdom and Canada have made significant investment in precision medicine that is underpinned by convergence science. An increasing number of organisations have been established to facilitate co-location of researchers from a variety of disciplines. The most ambitious to date is the Francis Crick Institute, which is headed by Nobel Laureate Sir Paul Nurse. In the United States, organisations such as the Institute of Computational Health Sciences at the University of California, San Francisco have emerged to advance precision medicine. More recently, the United Kingdom announced the establishment of the Precision Medicine Catapult Network in the Cambridge Hub.

**Clinical and diagnostics genomics**

The rise of genomic methodologies in medicine has predominantly been driven by the advances in high-throughput next generation sequencing technology. However, its adoption into the clinic remains slow because ongoing research is needed to demonstrate clinical validity and utility. More research is also needed to better understand the genotype–phenotype relationship. Despite these challenges, there have been groundbreaking applications in cancer pharmacogenomics, preclinical diagnosis and prognosis, and disease susceptibility.

Victoria has led international efforts such as the Human Variome Project to address the many challenges posed by this emerging and dynamic field. Participation in global programs such as the International Cancer Genome Consortium, Global Alliance for Genomics and Health, Global Genomic Medicine Collaborative and Genome in a Bottle Consortium enable Victorian clinicians and biomedical researchers such as those in the Melbourne Genomics Health Alliance to foster greater international collaborations and partnerships and learn from other world-leading researchers.
Biomedical engineering

Biomedical engineering or bio-engineering is defined as the application of engineering principles, design concepts and approaches to medicine and life sciences for the improvement of healthcare and medical service delivery across the health continuum. In presenting the grand challenges of the twenty first century, the United States National Academy of Engineering has boldly declared that biomedical engineering will “fulfil the promises of Personalised Medicine”. Biomedical engineering with sub-disciplines such as biomimetic engineering, tissue engineering, bio-mechanics, robotics, bionics, computational engineering, and nano-engineering, is gaining prominence as demand for medical technology in the health system grows. Victoria has a long tradition of innovation in biomedical engineering. The most successful invention to date is the cochlear implant or bionic ear. Inter-disciplinary initiatives such as the bionic eye program at Bionic Vision Australia and Monash University will continue to build Victoria’s strengths in biomedical engineering.

In Victoria, government initiatives such as the proposed Aikenhead Centre for Medical Discovery and university initiated entities such as Monash Institute of Medical Engineering facilitate convergence science. Given the size of the Victorian economy, the challenge will be to bring together expertise and capability residing in Victorian universities and medical research institutes to build scale and scope for driving innovation and leadership in convergence science.

8. How can Victoria become more internationally competitive in an evolving field of precision medicine? What should be Victoria’s particular areas of expertise that need further support and development?

9. How can multidisciplinary global collaborations be fostered to enhance the understanding of genotype-phenotype relationships?

10. What are the challenges in offering new and emerging molecular diagnostic tests such as whole-exome and whole-genome sequencing?

11. How can clinical utility of genomics be demonstrated? What are the ethical challenges in this area?

12. How can Victoria build a critical mass of expertise and capabilities in convergence science to address challenges in genomics and related ‘omics, systems biology and genomics medicine?
Optimising big data and informatics

The digital age brings with it an unprecedented amount of data. Data-intensive sectors such as healthcare and biosciences are experiencing a data deluge. This is largely driven by the advances in high-throughput technology in genomics and related ‘omics research and the growing use of electronic health records, clinical registries and digital health technologies.

Victoria has numerous initiatives and programs to collect and use data and information for clinical research and practice, safety and quality improvement, and population health monitoring. However, there is no overarching strategy that supports, integrates and connects these activities. Many initiatives and programs also do not “close the loop” by including a plan to:

- develop information relevant for the patient and consumer to make informed choices
- integrate information into the clinical workflow for improved health outcomes.

Data collection without a strategic system-wide approach will result in a Victorian health system that is data rich but information poor.

Turning data into clinically actionable information remains a challenge, particularly in an era of precision medicine. Healthcare professionals and medical researchers are grappling with the volume, heterogeneity and complexity of data from an array of sources and of different types and formats. Getting high-quality data in the right format at the right time with the right analysis remains problematic because of:

- poor access and sharing of data
- the lack of standardised data and technology
- the inability to unlock valuable clinical information in electronic health records
- bottlenecks in clinical and genomics data analysis
- skills shortages in health services research, genomics research and genomics medicine.

Overcoming these challenges will require an interdisciplinary network of collaborators and partners, a scalable platform technology and availability of analytical tools and informatics researchers to retrieve, analyse, integrate, visualise and interpret data and information.

Better use of health and biomedical data such as those residing in clinical registries and electronic health records will enable:

- policymakers to improve:
  - the coordination of health service delivery
  - the safety and quality of care
  - population health management
- providers from hospitals and GP clinics to deliver the right treatment to the right patient at the right time
- patients to be better informed and empowered to be partners in their health and healthcare
- payers such as insurers to better assess healthcare risk and lower the cost of premiums
- the public to access the right information for optimising wellness
- pharmaceutical companies to improve patient stratification in clinical trials.

Questions

13. There are numerous Victorian biomedical datasets held by multiple stakeholders that are difficult to access for health and medical research. How can this be addressed? (Note this question takes into consideration the privacy, confidentiality, data protection and human research ethics requirements for the use of such data.)

14. What are the bottlenecks in clinical and genomics data analysis? How can these be addressed?

15. How can the skill shortages in bioinformatics and health and biomedical informatics be addressed?
Implementing a world-leading clinical trials system

Victoria offers a strong foundation in clinical trials due to the state’s world-class hospitals, research facilities, healthcare workers and biomedical researchers. A robust clinical trials industry provides many health and wealth-associated benefits. Victorian patients are given access to the latest medical treatments, and clinical trials activity generates significant revenue.

Estimates suggest that annual Australian investment in clinical trials exceeds $1 billion, with Victoria’s share accounting for approximately 30 per cent. Estimates suggest that annual Australian investment in clinical trials exceeds $1 billion, with Victoria’s share accounting for approximately 30 per cent.30,31

Victoria’s Consultative Council for Clinical Trial Research is an advisory body to the Minister for Health and the Department of Health & Human Services. Victoria continues to drive improvements in clinical trials management processes in order to remain globally competitive. Some of the initiatives led by Victoria include the following:

- developing the National Mutual Acceptance approach for ethics approval for multi-centre clinical drug trials. This system streamlines the ethics approval process across all participating jurisdictions
- developing metrics and AU-RED functionality, including online application. AU-RED is the research ethics database software that captures data for all clinical trials in Victoria. Queensland, South Australia and New South Wales also use AU-RED to capture information on the regulatory processes for clinical trials including ethics approval times and progress
- the four national mutual acceptance participating states have connectivity in AU-RED to enable the capture of multi-jurisdictional trials. An initiative for national annual aggregate statistics will enable trial numbers to be measured and performance of clinical trials compared Australia-wide.

Despite these measures, challenges remain. The pharmaceutical industry has consistently voiced its concerns about the lack of efficiency in Australian clinical trial approval processes and performance including timeliness, consistency and reliability. Timeliness is evidence that jurisdictions and sites are meeting preapproval time targets (ethics and site approval). Consistency means developing a system to ensure that common approaches can be followed within and between institutions (including costing methodology and governance approval). Reliability is delivering what is promised, particularly regarding recruiting the agreed number of trial participants and completing the trial within the agreed timeframe.

The NHMRC, the Commonwealth Department of Health and the Commonwealth Department of Industry and Science are working with the states and territories to apply a nationally consistent approach to clinical trials that includes streamlined and timely ethics approval, site assessment and site authorisation processes. The NHMRC has recently implemented a ‘good practice process’ pilot to collect data on whether the streamlined good practice process leads to shorter lead times for beginning clinical trials. Four clinical sites in Victoria are participating in this pilot.

Another challenge in Victoria is the underutilisation of key assets for clinical trials. Recent Swedish and North American studies have shown that registry-based randomised trials could be undertaken at a fraction of the cost of running traditional clinical trials.33–35 Victoria could therefore explore approaches to better position the state’s high-quality registries for use in national and international multicentre clinical trials.

Without continued improvements to the state’s clinical trial system and optimised use of relevant state-funded assets, Victoria stands to lose its international competitiveness, and therefore its market share, to not only traditional markets in North America and Europe but also to emerging clinical trial markets in Asia and Latin America.

Questions

16. How can Victoria work more effectively with the NHMRC and the other jurisdictions to improve the clinical trial system to be globally competitive?

17. What would be the most effective way for Victoria to attract clinical trials and increase clinical trial participant recruitment?

18. How can the Victorian Government help to facilitate investigator-initiated clinical trials?

19. How can the clinical registries in Victoria be better utilised for clinical trials?
Developing the next generation health and medical research workforce

In 2013 the national health and medical research workforce was estimated at 23,000. This workforce is divided into those who are trained in medicine, nursing or allied healthcare practices and science, and those in supporting disciplines such as biostatistics and bioinformatics. Each of these groups face different challenges in the areas of training, career progression and job security. Clinicians often face barriers to participating in research, while PhD students and scientists may be confronted by issues related to career progression, security and remuneration.¹

The health and medical research workforce also faces limited support for gender equity. Recently, two prominent Australian leaders in health and medical research independently drew attention to the low number of women appointed to senior positions in academia and the lack of support provided by most institutions to retain and promote women in medical research.³⁶,³⁷ The NHMRC has begun to address this with initiatives such as:

- better balanced representation between men and women on peer-review committees
- the NHMRC Women in Health Science Committee
- revising the NHMRC’s administering institution policy to place greater emphasis on gender equity.

More recently, the NHMRC hosted a workshop about these issues. The findings from this workshop will inform the development of a strategy for the NHMRC’s Research Committee in improving the gender equity of women in health and medical science in the future.³⁸

As the NHMRC highlighted: ‘NHMRC cannot do it alone; sector-wide change is required. Change will require organisational change, behavioural change, structural change and cultural change.’³⁸

The health and medical research workforce would also benefit from greater participation and placement of researchers within industry to better understand respective unmet needs and challenges. Building research assets and infrastructure is critical to facilitating advances in medical research; however, it is also critical to build the capacity of the workforce to ensure optimum utilisation of these assets.

Questions

20. How can the Victorian Government in partnership with the academic and industry sectors best incentivise the retention and attraction of health and medical research talent to Victoria?

21. What programs could be enhanced or opportunities developed to support the career development of clinician scientists in Victoria?

22. How can women in biomedical research be better supported to progress to senior academic appointments?

See also the other sections for workforce-related questions.
Advancing international collaborations, industry-research engagement and innovation

Victorian health and medical researchers proactively engage with international partners and collaborators. Their success in international partnering and collaboration can be seen by their participation in programs funded by in-country funding agencies such as the National Institutes of Health (United States), the Wellcome Trust (United Kingdom) and specific European Union funding programs such as the European Research Council’s IDEAS program and the Forum for European–Australian Science and Technology Cooperation.

The NHMRC incentivises Australian researchers to engage in multinational collaboration through funding programs such as the NHMRC–European Union Collaborative Research Grants scheme as part of the EU Horizon 2020 program (€80 billion of funding available over seven years from 2014 to 2020).39,40

Victoria could benefit from a more strategic approach to supporting health and medical researchers in accessing significantly higher amounts of funding from overseas funding bodies.

Innovation in Victoria

Innovation is one of the key factors that drives Australia’s economic growth. Yet according to the Australian innovation system report 2014, the country’s innovation system is a mid-range performer compared with our Organisation for Economic Co-operation and Development (OECD) counterparts. The report flags that ‘Collaboration between research and industry is one of the lowest in the OECD. Industry–research collaboration on innovation by Australian SMEs [small to medium enterprises] is ranked 29th out of 30 OECD countries, and large firms are ranked 30th’.41 The recently released Global Competitive Report by the World Economic Forum (WEF) reinforces the need for Australia to improve public and private collaborations. The WEF report also highlights Australia’s poor performance in innovation, with low rankings for ‘technological readiness’ (19th) and ‘innovation’ (25th).42 These rankings would need to improve for Australia to be globally competitive.

To boost Australia’s global competitiveness, and to stimulate innovation and job growth, the Commonwealth Government is establishing Industry Growth Centres across the country. This initiative is focusing on five growth sectors that are outlined by the Commonwealth Government as areas of comparative advantage: medical technologies and pharmaceuticals; food and agribusiness; mining equipment; technology and services; advanced manufacturing; and oil, gas and energy resources. This program is inspired by overseas public–private partnership programs such as the United Kingdom’s Catapult program, which establishes innovation centres to bring together businesses, scientists and engineers to work on applied research and development projects. Of particular interest is the launch in July 2015 of the Precision Medicine Catapult Network in the Cambridge Hub.24

For Victoria, there is an opportunity to leverage the Commonwealth programs and build on state programs that provide incentives for the health and medical research sector to collaborate with industry and the international research community. Of importance are programs that showcase the collective expertise, capabilities and capacity of the Victorian health and medical research sector to domestic and international industries, and investment and philanthropic sectors.

Questions

23. How can the Victorian Government support the health and medical research sector to access more funding from international sources? What type of funding structure would facilitate co-investment from overseas organisations such as the Wellcome Trust (United Kingdom) and INSERM (France), which may be interested in partnerships with Victorian researchers?

24. How can the Victorian Government foster greater research–industry engagement that attracts multinational companies to Victoria?

25. How can the Victorian Government foster more effective collaborations between clinicians and academic medical researchers with those from the venture capital and industry sectors such as medical technology, biotechnology, pharmaceutical and ICT?
Australia, and particularly Victoria, is internationally recognised as a world leader in biomedical research. In regard to research publications, Australia punches far above its weight by producing 3 per cent of global research publications with only 0.3 per cent of the world’s population. However, compared with international standards, Australia has a poor record of commercial translation and is not adequately capitalising on discoveries.43 This poor record is exemplified by global commercialisation benchmarks such as triadic patents, which show that Australia has one of the lowest per capita numbers of such patent applications filed per year in the OECD.44

“Australia does an outstanding job of innovating, especially in the early research phase, only to leave a public policy gap that allows our technologies to leave our shores just as we are able to reap the greatest benefits from them.”43

There are arguably several reasons for Australia’s poor record in commercial translation. This may be attributed to the paucity of funding for preclinical and early clinical research and the absence of a local major pharmaceutical industry. There is also evidence of a weak commercialisation environment with insufficient commercialisation and intellectual property (IP) protection acumen among the research community. Minimising the loss of IP that results from delay, ignorance of its potential or unawareness of its existence is critical to commercialisation success. However, many researchers lack the capabilities and experience to identify and manage IP, develop investment proposals and manage dealings with commercial sponsors.1 Compounding this problem, much of the health and medical research community, including hospitals, medical research institutes (MRIs) and universities, do not have adequate access to the commercialisation expertise that is needed to identify and progress their research. Indeed, both the McKeon Review and the Association of Australian Medical Research Institutes have espoused the need to pool the groups of commercialisation expertise in Australia’s MRIs, universities and hospitals into larger and more powerful bodies.

The research community may also be faced with the dilemma of whether to publish or patent. In an environment where success, and indeed eligibility for grants, is determined by one’s number of publications in high-impact journals, incentives to commercialise discoveries are minimal.46 Additionally, the ratio of Australian researchers employed in business relative to higher education is significantly lower than the global average. In most developed countries this ratio is 2, while in Australia this is only 0.4.1

“There is clear value in supporting the commercialisation of health and medical research in Australia along the developmental chain, especially in the preclinical and early clinical trial stages where appropriately-targeted support could provide the necessary stimulus to convert ideas into real products and services.”1

Questions

26. How can intellectual property generated from publicly funded research be unlocked to accelerate innovation?

27. What are the key elements or features of a health and medical research innovation hub or centre that would contribute to effective commercialisation outcomes?

28. What programs could be implemented to provide the next generation of Victorian innovators in health and medical research with entrepreneurial, commercialisation and business skills and capabilities?

29. What is a model for engagement with international innovation programs, such as the US-based Stanford Bio-Design program, that would enable Victorian innovators to build industry-specific experience and capabilities?
Optimising funding models and sources

Adequate sources of funding are critical for enabling the scientific and technical research needed to underpin innovation, improve health outcomes for the community and increase economic growth. Health and medical research income to Victoria is predominantly through NHMRC national competitive grant revenue, which is largely administered through universities, MRIs and health services.

Other health and medical research-related funding is obtained through the ARC, the CRC program, the Medical Research Commercialisation Fund, international grant income, philanthropic granting bodies, Victorian government-funded statutory bodies and agencies such as VicHealth, and commercial income such as revenue from clinical trials.

Funding for the commercialisation process

Funding is required at three key stages in the health and medical research commercialisation process: preclinical, early clinical and late clinical. However, the inappropriate targeting and inadequate funding in the first two stages had led to them being coined the ‘twin valleys of death’ (see Figure 3). Current sources of funding at the preclinical stage include:

- the NHMRC Development Grants scheme
- ARC Linkage Projects scheme
- Accelerating Commercialisation program that provides matched funding to bring IP to market for early-stage commercialisation.

However, the commercial criteria that the NHMRC Development Grant applicants are required to meet are unrealistic and onerous, and grant assessments place undue emphasis on a track record of commercial success. Restrictions placed by the ARC Linkage Project scheme on clinical research significantly reduce the health and medical research sector’s eligibility to apply for this scheme. Additionally, the limited timelines for grant outcomes required by the Commonwealth Government’s Accelerating Commercialisation program for commercial product development do not align with the lengthy periods that medical product development usually requires.

Another limitation of the scheme is its failure to fund research such as clinical trials, which are a necessary part of the commercialisation process. The current avenues for funding at the early clinical stage include:

- the Commonwealth Government’s Innovation Investment Fund including the Medical Research Commercialisation Fund (note: as part of the 2014–15 Federal Budget, the government has decided not to proceed with additional rounds of funding for this program)
- other private sector funds that target the biotechnology, medical technology and pharmaceutical sectors.

Indirect costs of research

The funding that universities, MRIs and hospitals receive via external grants from the NHMRC, ARC and philanthropic trusts usually only covers the direct costs of research. Funding for indirect costs is covered by two federal funding schemes:

- Research Infrastructure Block Grants and the Sustainable Research Excellence in Universities scheme, which provide support exclusively to university-based research
- the Independent Research Institutes Infrastructure Support Scheme, which is provided as a fixed fraction of direct funding from NHMRC grants.

At the state government level, the Operational Infrastructure Support program provides annual funding to eligible Victorian independent medical research institutes towards the overhead costs of their research.

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 undertake research.
Questions

30. How could the siloed funding mechanisms in Australia be changed to facilitate greater collaboration?

31. As early-stage translation research such as proof-of-concept studies has difficulties in attracting investment, what funding model would best address this challenge? How could the National Institutes of Health’s Small Business Innovation Research (SBIR) program (United States) or the Catapult program (United Kingdom) be applied to the Victorian setting?

32. How can the Victorian Government assist in promoting the value of Victorian health and medical research to the philanthropic sector?
Part 3: Next steps

The Department of Health & Human Services is seeking input from the health and medical research sector on how the department can best support and further develop health and medical research in Victoria. Stakeholders are invited to provide feedback on the questions (listed below) relating to the themes described in this discussion paper. Stakeholders are also invited to detail five to 10 health and medical research-related actions that are considered to be the most critical to improving the health and wellbeing of Victorians.

All written and verbal feedback received will be carefully considered and will inform the development of the Victorian health and medical research strategy.

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<th>Questions</th>
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<td>1. What are the areas of greatest strength in translation research that Victoria could build on and what criteria should be used to determine this?</td>
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<td>2. How can these strengths be enhanced to ensure Victoria has the critical mass and scale to be globally competitive or what strengths does Victoria need to develop?</td>
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<td>3. What are the five priority areas of focus for health and medical research in Victoria over the next five years based on Victoria’s strengths and needs?</td>
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<td>4. How can the performance of Victorian academic health sciences centres be optimised to advance research, education and healthcare?</td>
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<td>5. What are the top areas of priority for health services research in Victoria?</td>
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<td>6. What are the skills shortages and other current deficits in health services research? How can Victoria address these shortages/deficits?</td>
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<td>7. What are the barriers to translating health services research into practice and policy? How can these barriers be overcome?</td>
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<td>8. How can Victoria become more internationally competitive in an evolving field of precision medicine? What should be Victoria’s particular areas of expertise that need further support and development?</td>
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<td>9. How can multidisciplinary global collaborations be fostered to enhance the understanding of genotype-phenotype relationships?</td>
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<td>10. What are the challenges in offering new and emerging molecular diagnostic tests such as whole-exome and whole-genome sequencing?</td>
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11. How can clinical utility of genomics be demonstrated? What are the ethical challenges in this area?

12. How can Victoria build a critical mass of expertise and capabilities in convergence science to address challenges in genomics and related ‘omics, systems biology and genomics medicine?

13. There are numerous Victorian biomedical datasets held by multiple stakeholders that are difficult to access for health and medical research. How can this be addressed? (Note this question takes into consideration the privacy, confidentiality, data protection and human research ethics requirements for the use of such data.)

14. What are the bottlenecks in clinical and genomics data analysis? How can these be addressed?

15. How can the skill shortages in bioinformatics and health and biomedical informatics be addressed?

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References


