

Victorian health and medical research strategy

Discussion paper 2015

Submission from Biomedical Research Victoria

Biomedical Research Victoria (BioMedVic) is the leading member organisation representing Victoria's diverse and remarkable health and medical research community of academic hospitals, universities, independent medical research institutes and CSIRO.

BioMedVic's vision is for Victoria to be recognised as a global leader in health and medical innovation, improving health and creating wealth, and the organisation is dedicated to supporting its members to deliver innovative, world-class health and medical research.

We provide a structure for promoting collegiality and inter- and multidisciplinary research collaboration and seek to increase community understanding of advances in health and medical research and the many positive impacts this research has on Victoria's economy and the health of Victorians.

Biomedical Research Victoria applauds the Victorian Government's substantial and sustained investment in medical research and innovation and appreciates the excellent and timely overview of the achievements and challenges facing the state's health and medical research sector provided in the Victorian health and medical research strategy Discussion paper.

BioMedVic supports the Government's vision for the Victorian health and medical research strategy to optimise wellbeing and improve the health outcomes of Victorians and its dual objectives to embed health and medical research into the health system with a view to accelerating the translation of research outcomes into the clinic and community.

Given the relatively short timeframe for consultation we have not attempted to be exhaustive in our response but rather focus on those first order strategic matters in the discussion paper that BioMedVic believes will have greatest influence on the Government's ability to realise its vision and goals for the sector. We would welcome the opportunity to meet to with the Department to expand on our responses.

It is also noted that this submission is made on the collective behalf of the members of Biomedical Research Victoria and is additional to the individual submissions we understand have been made by many of our member organisations.

At a time when it could be argued that Victoria is in danger of being surpassed by other Australian states and is falling behind other centres in the region as a location to conduct research, deliver world class clinical outcomes and establish new industries, BioMedVic believes that Victoria needs a long term science and innovation plan that has bipartisan support, is overseen by a senior Minister and is well coordinated across the whole of government.

In this context, the parallel release by the Departments of Health and Human Services (DHHS) and Economic Development, Jobs, Transport and Resources (DEDJTR) of two discussion papers affecting the sector is intriguing.

BioMedVic urges the Government to consider developing a comprehensive Victorian Health and Medical Research and Innovation Plan that:

- includes medical technologies (medtech) and pharmaceuticals
- envisions the creation of critical mass and thereby global competitive advantage for Victoria through horizontal cooperation between government, research, education, healthcare and business
- recognises the potential of health and medical research to generate wealth and other economic benefit for Victoria through
 - jobs creation within the sector & in allied industries (eg: legal, finance; CROs, cGMP)
 - local manufacturing based on Australian IP
 - export of finished pharmaceuticals, products, medical technologies and valuable intermediary components
 - licensing of IP
 - establishment of R&D collaborations
 - sale of Victorian biotechnology companies
- provides a framework that will support efficient inter-Departmental operations & minimise confusion in engagement with external stakeholders.

However, recognising that politics will likely prevail, BioMedVic believes it is critical that the Health and Medical Research Strategy and the Medical Technologies and Pharmaceuticals Sector Action Plan be complementary and synergistic in relation to their scope & operation and the eligibility of stakeholders for government support.

In times of constrained resources the Government needs to build on areas of greatest strength in translation research in Victoria. BioMedVic recommends that such strategic focus be placed on those areas and capabilities in which Victoria is or has the potential to be a world leader, and thus has a competitive (innovative) advantage, and in which the clinical and economic benefits can be captured.

Some suggestions are:

- Biomedical engineering including bionics and the design & development of medtech devices
- Infectious disease research & development of safe & efficacious prototype vaccines
- Neuroscience including mental health & dementia
- Discovery, development, optimisation & delivery of new drug treatments
- Immunity & Inflammation
- Regenerative medicine
- Diabetes & metabolic disorders – includes cardiovascular & obesity

BioMedVic recommends the criteria to determine those areas of greatest strength in translation research include:

- clearly identified unmet need & demand for the product, clinical solution, treatment, device, health service reform or process improvement
- international reputation with world-class clinical & academic track record in the field
- appropriate & collaborative inter- and multidisciplinary team that may exist or can be assembled with the right composition at the right time
- existing IP or at least a pathway for creating IP
- understanding of market size & quality with assured market access and knowledge
- understanding of the research, clinical & commercial competitive landscapes in the field, market or market segment
- critical development pathway mapped and costed with Go/No Go points, key inputs, regulatory hurdles & success criteria for each stage gate defined
- evidence of appropriate financial, legal, management & governance processes in place
- based on the above criteria, an assessment of ability to attract & secure large scale private sector investment in due course

To enhance these strengths to ensure Victoria has the critical mass and scale to be globally competitive, BioMedVic believes the Government should:

- Support the state's health and medical research strategy with a science and innovation Fund established by consolidating monies already allocated to support the sector plus an injection of new money
- Establish an expert advisory panel comprising experienced and independent members with successful track records in investing in medical research and its commercialisation, and whose expertise is augmented by that of senior representatives from Treasury, DHHS & DEDJTR.
 - Charge the panel with responsibility to put suggested strengths through a sieve of objective criteria (see above) to assess whether they indeed represent opportunities where Victoria is world-leading or has the potential to be so
 - The expert advisory panel would propose Fund investment recommendations to the responsible Minister on which strengths, capability &/or infrastructure should be supported (how much, how long & at what stage) as well as make recommendations about other forms of support that may be appropriate (eg: strategic PPP)
 - By corollary the expert advisory panel through its activities would also confirm for Government which areas should not be pursued at a particular time & why not
- Stimulate innovation by incentivising clinical & research teams that may be working separately between and within precincts on the same or similar areas of strength to work cooperatively for the sake of the mutual benefits they could receive, not the least of which may be government support for their research leading to enhanced productivity and research impact, efficiencies of scale, cost-competitiveness and reduction in red-tape
- Ensure state government policy settings provide incentives for relevant industries to establish themselves in, or relocate to, Victoria (eg: favourable state land & payroll tax rates; and targeted lobbying of the federal government for the introduction of a highly targeted

differential corporate tax rate for advanced manufacturing based on Australia IP¹ and enhanced eligibility and rates of assistance under the R&D Tax Incentive.)

Once established, the Fund should be strategically deployed to:

- provide early stage capital for translation research proof of concept studies to enable promising R&D projects for new treatments, products and life-saving technologies to develop a body of data that makes them ready and attractive for private investment (with a likely upside being the creation of jobs)
 - there are a number of international funding models for support of such studies that could well be applied in Victoria including the UK Catapult program, the NIH SBIR and STTR programs, the Massachusetts Clinical Innovation Gateway and CIMIT
- BioMedVic would be pleased to provide our highly-regarded blend of research and industry skills and resources, gained in both the public and private sectors over many years, in any way that the Government feels would be helpful to evaluate the options and/or once a decision has been made to ensure that such a program operates within guidelines established by the Government to best support Victoria's areas of greatest strength in translation research
- provide support for incubators that link research centres creating new technologies to industries capable of exploiting them
- provide dedicated infrastructure support for Medical Research Institutes (MRIs) and, where appropriate, for encouraging shared use of common services and rational mergers or amalgamations
- ensure that research is truly embedded in academic hospitals and that funds provided for such research and its related infrastructure are used for this purpose through the reinstatement of research (+/- teaching & training) in the activity-based funding agreements for health services and the introduction of key performance indicators for research impact in the employment contracts of Victorian hospital CEO's
- support a limited number of Academic Health Science Centres (AHSCs) whose role it is to provide world class leadership in training, clinical research and its translation
 - by defining the agenda for the AHSCs and ensuring that they are led by the health services (in consultation with DHHS) and that appropriate governance and management processes are in place to support the delivery of goals, government can optimise AHSC performance for maximum output and impact in return for a secure funding stream
 - government should consider allocating money to a central body to which Victoria's AHSCs would 'bid' for project funding (via a CIMIT-Like model – see above)
 - BioMedVic suggests that AHSCs should focus on projects that will
 - improve health service delivery
 - increase the efficiency of the health service / system
 - lead to the rapid translation of knowledge into new treatments, pharmaceuticals, devices, diagnostics and other outcomes for which an unmet need & demand has been established

¹ <http://www.csl.com.au/Newsroom/Australia-Innovation-System-Could-Deliver-More.htm>

- provide major items of new infrastructure (eg: shared bioresources facilities, high performance computation for data analysis for ‘omics, bioinformatics & medical imaging)
- maintain the Victorian Platform Technologies Network (VPTN); an invaluable source of competitive advantage for Victoria, the VPTN is a centralised, open & cross-institutional network of over 150 platform technologies located in >30 organisations that helps to connect publicly-funded research infrastructure and capability (expertise) with industry and researchers
- increase the number of fellowships for Australian and international researchers or groups that are world-class in the agreed areas of greatest strength in translation research to encourage them to choose Victoria as the place to establish themselves as independent researchers
- provide specific fellowships to help define and secure career pathways for Victoria’s established and early-career clinician-researchers (including doctors, nurses and allied health professionals)
 - Data published in 2014² from a survey of BioMedVic’s Victorian Clinician Researcher Network (VCRN) established that the biggest barrier to translation of research to beneficial patient outcomes was the lack of protected research time due to clinical commitments.
 - VCRN co-convenor A/Prof Andrew Wilson’s own research concluded that a *“range of factors are impacting on the ability of the health system to attract and retain the best minds in clinical research roles. These include inconsistent and fragmented funding models, significantly reduced levels of funding and extended training pathways, the combined outcome of which is a critical reduction in the number of people with advanced academic skills and qualifications seeking clinical research roles.”*³

In relation to questions in the discussion paper on health services research and clinical trials, BioMedVic will be pleased to convene three of its expert networks – the Hospital Research Directors Forum (HRDF), the associated Hospital Research Managers’ Subcommittee and the Victorian Clinician Researcher Network – to share their knowledge and first-hand experience and expertise to assist the Government determine:

- the top areas of priority, the skills shortages or other deficits and the barriers to translating health services research into practice and policy, and
- the most effective way for Victoria to attract clinical trials, increase clinical trial participant recruitment to target and utilise its highly-skilled human capital and clinical registries.

It is noteworthy that BioMedVic has slated a national/international conference focused on health services research for 2016; input from the Government on the agenda and key presenters is welcome.

In general, Victorian clinician researchers enjoy a good working relationship with the NHMRC on activities to improve the Australian clinical trial system. For example, BioMedVic’s CEO chairs the NHMRC Research Governance working group of national health services and jurisdictional representatives (includes the Deputy Chair of HRDF but no DHHS representative) that has guided

² Hiscock H. *et al* Internal Medicine Journal 2014 44(5):477-482

³ Wilson A [Intern Med J.](#) 2007 Nov;37(11):778-81

development of a [‘Good Practice Process’](#) for site assessment and site authorisation phases of clinical trials research governance. Victoria has 5 of the 16 national pilot sites to test the implementability of the streamlined process over the next 6-12 months. BioMedVic also regularly hosts senior members of the NHMRC Clinical Trials Section at meetings of the HRDF whose collective expertise and feedback is readily acknowledged as being valuable to the NHMRC. BioMedVic has observed that the HRDF is not regarded as a resource in this same way by DHHS and hears, at least anecdotally, that Victoria may not be as cooperative as other jurisdictions in the national conversation on clinical trials.

Over the past three years BioMedVic has also witnessed much parallel and seemingly uncoordinated activity across the state’s health services in relation to (i) collecting, analysing and sharing of patient and other data for healthcare, training, research & clinical trials and (ii) streamlining research ethics and governance processes.

While there are many opportunities to demonstrate leadership, for example by mandating adoption by health services of uniform health information exchange solutions, a pressing role for Government in enhancing Victoria’s economic development would be to align and coordinate activity around research ethics and governance processes with a view to achieving state-wide efficiencies of scale and processes that would combine to make Victoria a reliable and attractive destination for the conduct of sponsored and investigator-initiated clinical trials. In this context, BioMedVic also wonders about the operation of the Victorian Consultative Council for Clinical Trial Research (CCCTR) within DHHS and consequently whether the CCCTR is able to realise its full potential as an advisory body to the Minister for Health on matters pertaining to the conduct of clinical trials and associated human research.

The Victorian Government should consider supporting the health and medical research sector to access funding from non-state government sources (eg: NHMRC, ARC, the CRC program, Industry Growth Centres, MRFF, Gates Foundation, Wellcome Trust, philanthropic organisations) by utilising and resourcing an organisation like BioMedVic to first catalyse the formation of “taskforces” comprised of appropriately skilled individuals and groups and then coordinate development and submission of the best possible bid from Victoria for submission to the specific agency offering funding.

Specifically in relation to the MRFF, Victoria may be able to position itself favourably over other jurisdictions and the special pleadings of the nation’s universities and MRIs by nominating an experienced and independent individual with a successful track record in medical research and its commercialisation for membership of the Australian Medical Research Advisory Board.

Last, the notion that “convergence scientists are a new class of researcher...” is fanciful. Successful researchers have long exhibited the ‘behaviour’ of silo-busting and the crossing of boundaries to seek out and engage with others who offer new knowledge, clinical expertise, enabling technologies and disruptive thinking – it’s what characterises researchers that are recognised as international leaders for innovation in global health.

Simply saying that research has been embedded into the health system or by creating more networks will not ensure the goals of the state’s health and medical research strategy are achieved.

Instead, BioMedVic suggests that the Government encourage real collaboration that’s competitive but not cannibalistic, by designating and funding Victoria’s health and medical research precincts.

Involving a tertiary academic hospital, Victoria's first precincts could achieve critical mass by being centred around the AHSCs – MACH, MPAHSC and the Western Alliance in the first instance – but with a composition that's neither prescriptive nor invariant including as appropriate MRIs, universities, university clinical schools, Primary Health Networks, private & public hospitals, biotechnology entrepreneurs and access to a range of industry I with design, IP (including invention identification, capture, protection & prosecution, freedom-to-operate analysis, disclosure considerations), legal and commercial nous).

Adequate support of such precincts will make best use of Victoria's highly skilled workforce, stimulate innovation through cross fertilisation of ideas and knowledge between clinicians, researchers, students, investors, IP professionals, regulatory and commercialisation experts, and ultimately facilitate the effective translation of research findings into clinical practice and economic benefit.

Biomedical Research Victoria would welcome the opportunity to meet with the Department to expand on our responses.

Please direct any questions about this submission to me at jan.tennent@biomedvic.org.au or on (03) 8344 1937.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'J. Tennent', with a stylized flourish at the end.

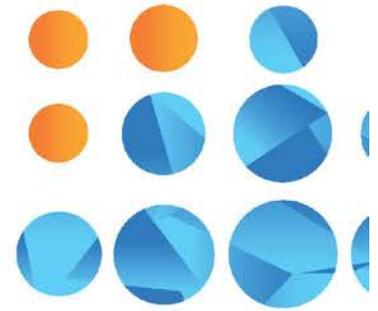
Assoc. Professor Jan Tennent
Chief Executive Officer

on behalf of the Board and Members of Biomedical Research Victoria



BIOMEDICAL RESEARCH VICTORIA

INNOVATING FOR HEALTH



- Alfred Health
- Austin LifeSciences
- Bionics Institute
- Burnet Institute
- Cancer Trials Australia
- CSIRO
- Deakin University
- Melbourne Health
- Monash Health
- Monash Institute of Pharmaceutical Sciences
- Monash University
- Murdoch Childrens Research Institute
- Neurosciences Victoria Ltd
- Olivia Newton-John Cancer Research Institute
- Orygen
- Peter MacCallum Cancer Centre
- St Vincent's Hospital (Melbourne)
- St Vincent's Institute of Medical Research
- Swinburne University of Technology
- The Florey Institute of Neuroscience & Mental Health
- The Royal Children's Hospital
- The Royal Women's Hospital
- The University of Melbourne
- Victorian Comprehensive Cancer Centre
- Walter and Eliza Hall Institute of Medical Research
- Western Health

AlfredHealth

Austin LifeSciences



MELBOURNE HEALTH

MonashHealth

MONASH University
Pharmacy and Pharmaceutical Sciences

MONASH University

Murdoch Childrens
Research Institute



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Olivia Newton-John
Cancer Research Institute

