

PCFA'S RESEARCH PROGRAM STRATEGY 2013-2017



PCFA would like to recognise the Movember Foundation as the key funder of its National Research Program.



ACKNOWLEDGEMENT OF CONTRIBUTION

The following experts and consumers contributed to the strategy and vision of PCFA's Research Program 2013-2017 included in this summary:

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A MESSAGE FROM DR ANTHONY LOWE



Funding prostate cancer research on a competitive basis with the aim of reducing the burden of prostate cancer nationally has been one of the major goals of PCFA. Research funding dates back to 2004 when we first awarded two fellowships to talented postdoctoral fellows, Dr. Lisa Butler and Dr Sue Henshall, both of which have gone on to be promoted to Associate Professor and conducting independent cutting edge research.

Since then, thanks to the generosity of Movember, we have invested nearly \$30M in prostate cancer research nationally. An evaluation of PCFA's investment in prostate cancer research since the establishment of its structured program in 2007 has shown that this funding has had a major impact in our community. This is reflected in the number of published peer review articles, translation of research findings and number of trained scientist that will become the leaders of tomorrow.

Completed and ongoing research continues to deliver outcomes which have contributed to a high level of innovation and increased Australian prostate cancer research profile. Importantly, the increased profile of prostate cancer research nationally and internationally has helped to ensure that prostate cancer research has a place on the policy agenda and raises community and philanthropic awareness.

Funding provided through our national program has mostly been catalytic. However, the availability of this seed funding has increased research capacity that might otherwise remain immature. This is reflected in the progress of a number of projects across the board.

Application of research findings locally remains very high in PCFA's priority agenda. We are confident that to date the program has achieved that and that specific research programs have been implemented and have already had a positive impact in the quality of life of Australian prostate cancer survivors.

We are proud of these achievements and look forward to continuing to make significant impact in the field by providing the financial support needed to find better tests for the diagnosis of prostate cancer, to accelerate the pace of discovery of new therapeutics and to better manage the disease for those living with prostate cancer.

However, the burden of this disease in our country remains high. Changing the current statistics will require a major effort on the part of our research community, better collaboration, higher rates of translation of research results and achievements that warrant changes in the current standard of care and policy.

I believe that our new priority driven funding approach has taken into account some of the changes that need to be made in order to achieve these results and, at PCFA, we look forward to a close collaboration with the research community to deliver the major objectives of our five year research funding strategy.

A handwritten signature in black ink that reads "Anthony Lowe".

Dr Anthony Lowe
Chief Executive Officer

A MESSAGE FROM PROFESSOR JOHN MILLS



It gives me great personal pleasure to see the PCFA research strategy for the next five years released. This important document outlines the goals of the PCFA Research Program through to 2017, and specifies the methods that will be used to reach those goals.

This strategy document represents hard work, and deep thought, by many individuals.

I am most grateful to Dr Miranda Xhilaga and Anne Maerz, who did the hard yards in pulling together and analysing an enormous amount of information about the 2007-2012 research program's achievements. This information formed a solid platform which was essential for the subsequent discussions and decisions which led to the 2013-2017 strategy. Miranda and Anne also organized the several meetings which informed the strategy document.

A very large group of Australians actively participated in the "construction" of this research strategy.

The members of the Research Advisory Committee were critical to the success of the development process, and I am very grateful for their wisdom and keen support. In addition to their expertise, they brought a vast amount of experience gained from reviewing and prioritizing prostate cancer research grant applications over the past six years.

What came as a bit of surprise to me – a very happy surprise – was the interest and enthusiasm that many other stakeholders in prostate cancer research showed towards participating in the process of developing the research strategy. These individuals included Australian prostate cancer scientists – both young and less young, individuals affected by prostate cancer, either directly or indirectly, and directors and staff of PCFA itself. The knowledge, interest and enthusiasm that these stakeholders brought to the development process was invaluable, and I owe a real debt to them for that.

The research strategy outlined in this document will not necessarily please everyone. However, I am confident that it is the best path for the PCFA Research Program over the next quinquennium. And I suspect that support for this strategy will grow as it is implemented.

A handwritten signature in black ink, appearing to read 'J. Mills', written in a cursive style.

Prof John Mills

*Chairman, Research Advisory Committee
May, 2013*

A NEW ERA IN FUNDING PROSTATE CANCER RESEARCH IN AUSTRALIA

In 2012 PCFA has undertaken an evaluation of research investment into prostate cancer nationally since 2007 and a series of consultations with its major. Data obtained from this evaluation and recommendations steaming from two think tanks have enabled PCFA to:

- Identify a clear long term research funding strategy for consideration by the PCFA's National Board
- Establish a priority-driven National Prostate Cancer Research Action Plan.

The following recommendations were submitted following a Think Tank attended by 42 participants, prostate cancer scientists, individuals affected by cancer (Cancer Voices and members of PCFA Support Groups), Andrology Australia, *beyondblue*, Cancer Council Victoria, Cancer Australia, ANZUP, and Cancer Research Leadership Forum:

1. PCFA should continue its leadership initiative in facilitating the development of a national action plan for prostate cancer research and funding. A comprehensive plan developed within a consultative framework and including government and industry would, with funding and commitment, go a long way to addressing the needs of researchers, policymakers, healthcare providers and the ultimate stakeholders; the community.
2. PCFA should strengthen the current unique portfolio of prostate cancer research through concept awards, supporting investigator driven research and investing in Australia's intellectual capital through the young investigator programs.
3. PCFA should work towards supporting a collaborative and multidisciplinary research program.
4. PCFA should develop an early and mid-career funding mechanism to address the critical lack of opportunity within the existing NHMRC career awards structure.
5. PCFA should develop a long-term program to stimulate and support early and mid-career clinical scientists; there are international models that can inform this approach.
6. PCFA should include psychosocial research as a priority in addition to its biomedical focus.
7. Internationally, PCFA should work in partnership with other Prostate Cancer Foundations to identify common strategies and funding schemes.
8. PCFA should work with partners to review existing funding models and identify novel long-term investment approaches that include consideration of sustainability for successful research programs including essential infrastructure.
9. PCFA should establish effective communications strategies to address the needs of consumers, including their aspirations, to formally contribute to priority setting, research review and translation of research into practice and the dissemination of research findings to the broader community- there are other models which provide guidance in this area including the Cancer Council NSW, Cancer Australia and CanSpeak.
10. PCFA should work with the Cancer Australia and the Clinical Trials Cooperative to identify priorities and partnership funding opportunities and to increase funding support for investigator-driven trials through the Cooperative Trials Groups.
11. PCFA should increase professional development by challenging the current paradigm in regard to travel awards through new approaches that enable international networking and international exchange.

Clearly, resources (people and dollars) are not going to be able to support all these recommendations. They were therefore narrowed down to four main themes:

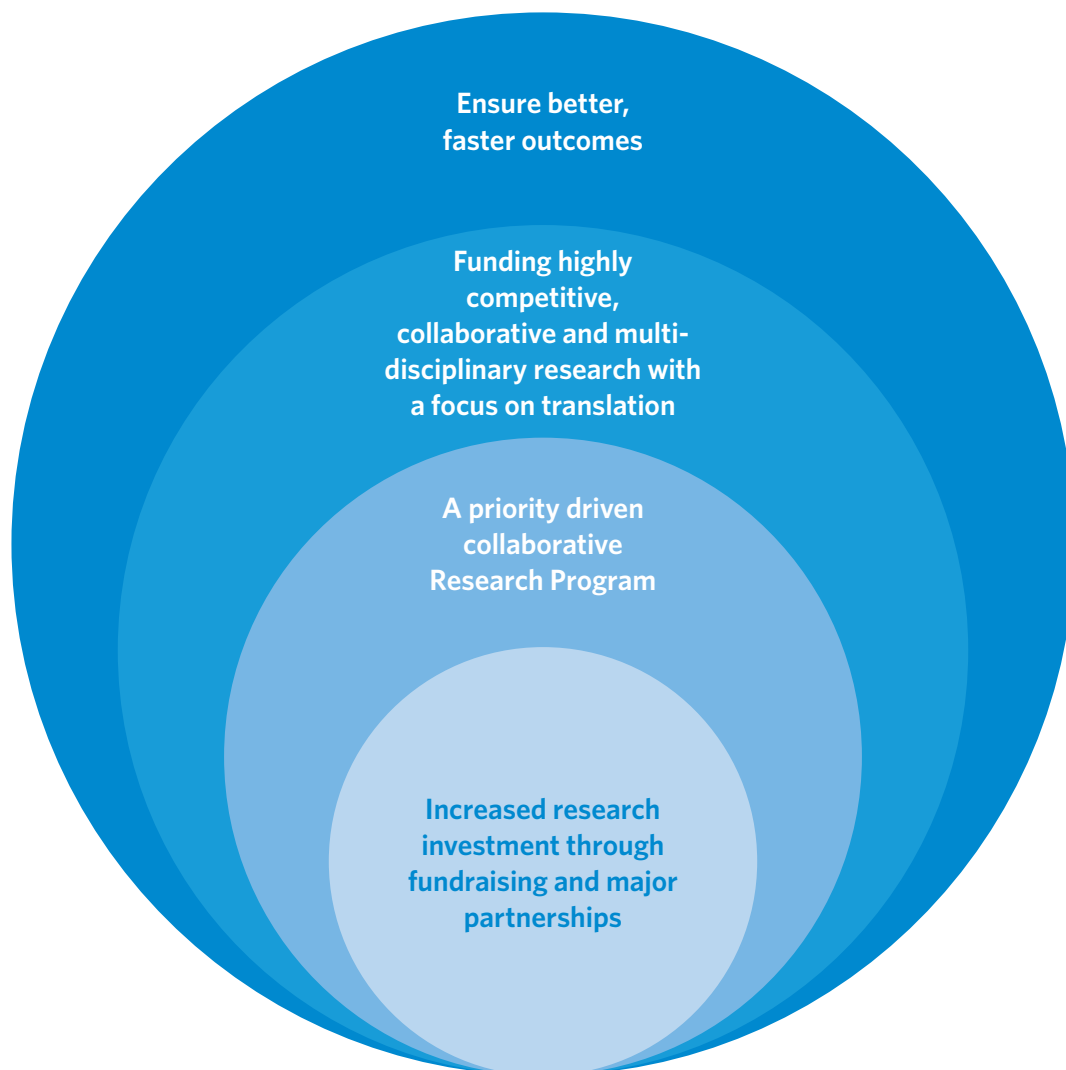
Funding: There is a need to grow PCFA's research funding base to enable funding of clinical, public health, psychosocial and multidisciplinary research, as well as clinical trials. Further, there is a need for "enabling" grants to support institutions engaged in prostate cancer research. This breadth of funding would only be possible if the funds available for the Research Program were substantially increased.

Collaboration: PCFA needs to develop grant structures that encourage greater collaboration, specifically nationally and also internationally. Collaboration yields unexpected new research hypotheses, and accelerates research outcomes.

Diversification: PCFA also desires greater emphasis on support for clinical trials, clinician researchers, translational research, psycho-oncology, social science research and other non-basic science research areas to broaden its research program. This would also include maintaining and reviewing priority areas and possibly the establishment expert driven sub-committees.

Priority Driven: Through reviews and consultation with prostate cancer experts and consumers PCFA will identify areas or priorities for funding, foster collaboration and ensure greater consumer participation in research via inclusion of consumer-driven priorities perhaps through the establishment a consumer sub-committee.

A PRIORITY- DRIVEN NATIONAL PROSTATE CANCER RESEARCH PROGRAM 2013-2017



“In order to improve outcomes in prostate cancer research in Australia, we need to build capacity and use that capacity more effectively through shared skill sets, translating research through relevant disciplines progressively, and we need to work together to improve prostate cancer management for the Australian men suffering from this disease. The common plank that bonds these aspirations is collaboration.”

Senior Prostate Cancer Researchers

PCFA’s new strategic, priority driven action plan aims to build on the success and outcomes of the past research investment and ascertain that milestones and discoveries made in the future will directly impact on the quality of lives of Australian men that are or will be diagnosed with this disease in the next five years.”

Research Advisory Committee, PCFA

MISSION

The mission of PCFA's Research Program is:

- **To make discoveries which will improve the length and quality of life of men with prostate cancer, especially prostate cancer which cannot be cured by surgery or radiation therapy.**

GOALS

1. *Improve the diagnosis, staging, characterization and treatment of prostate cancer, by providing funds which are distributed by a rigorous, scientific, transparent and fair process underpinned by strategic goals, and which as a result supports the top Australian prostate cancer research proposals.*
2. *Recognizing that accelerating the pace of this research will increase the number of prostate cancer patients who benefit from the research, we will provide research support which emphasises (1) **collaboration** (which clearly accelerates research outcomes) and (2) **translation** of research results through support for clinical investigators and clinical trials – to ensure that promising laboratory results are rapidly assessed in the clinic.*
3. *Continuing to increase the pool of independent prostate cancer scientists specifically by supporting young prostate cancer scientists and by providing a financial incentive for senior scientists in other disciplines to bring their expertise, creativity and technology to prostate cancer research.*
4. *Increasing innovation by supporting grants that specifically have that focus.*

FUNDING PRIORITIES

- Projects which if successful are likely to provide relatively immediate improvements in the quality of life of patients with prostate cancer
- Discovery, development and clinical validation of new, non-invasive tests to detect prostate cancer, and/or to determine whether a patient's cancer is curable
- Discovery, development and clinical validation of new biomarkers that predict the future clinical course of prostate cancer and/or the response to future chemotherapy
- Discovery, development and preclinical and clinical validation of novel, promising molecular targets for chemotherapy of locally-invasive or metastatic prostate cancer, including "castrate-resistant" cancers
- Development of new treatment strategies for prostate cancer, especially locally-invasive or metastatic cancers

OBJECTIVES OF PCFA'S RESEARCH PROGRAM

Australia has historically contributed to health and medical research out of proportion to its small population. On the basis of medical research publication benchmarks, Australia ranks 6th globally, eclipsing many countries with larger populations and economies. *However, we are now at a critical crossroads and decisions made now will affect research capability in Australia well into the future.*

PCFA's new strategic, priority driven action plan aims to build on the success and outcomes of the past research investment and ascertain that milestones and discoveries made in the future will directly impact on the quality of lives of Australian men that are or will be diagnosed with this disease in the next five years.

A PRIORITY- DRIVEN NATIONAL PROSTATE CANCER RESEARCH PROGRAM 2013-2017

This program will create new knowledge by:

- Increasing national and international collaboration and achieving impact through team efforts
- Accelerating research translation and enable support towards clinical trials
- Enriching and reviving the Australian prostate cancer research workforce
 - Ensuring that Australian prostate cancer research talent does not fall through the cracks of academia and that the future of prostate cancer research in Australia remains secure
- Seeking and supporting innovative ideas in prostate cancer research
- Enabling and sustaining prostate cancer research national networks in Australia
- Work in partnership with men's health partners and other cancer research funding organization to increase and coordinate cancer research funding
- Work closely together with the researchers and the community to set a priority research funding agenda in prostate cancer
- Implement a world class knowledge translation strategy

INCREASE COLLABORATION AND ACHIEVE IMPACT THROUGH TEAM EFFORTS

Collaborative research initiatives face many challenges such as: economic uncertainty (global economic uncertainty and its impact in R&D), fragmentation of knowledge (fragmentation of disciplines and associated need to build research groups that can marry complementary expertise), the associated cost of high impact research and demographic challenges. Financial constraint and slowing growth in research budgets in particular, could lead to less collaboration as researchers struggle to secure financial means to foster meaningful partnerships.

In Australia, government funding initiatives that stimulate bilateral international collaboration spread across all areas of medical research. Several funding schemes that are aimed at stimulating international collaborations are available on an annual basis: Australian Research Council (ARC) www.arc.gov.au/general/international_collaboration.html

Collaborative Research Networks (CRN) www.innovation.gov.au/RESEARCH; Australia-Europe Research Collaboration Fund <https://grants.innovation.gov.au>; The Australia-Netherlands Research Collaboration (ANRC) www.aust-neth.net/ etc. target either existing or new collaborative efforts intercontinentally or/and globally. *However, targeted initiatives in a specific field or tumour stream level are left to private individual agencies and institutions.*

The greatest and most significant breakthroughs in prostate cancer research around the globe in the past decade have all come from large clinical and scientific research teams, which are both highly collaborative within their team environment and with the national and international prostate cancer research community.

Overall, the prostate cancer research community in Australia achieves research excellence which is of an international standard. However, these *outputs are largely achieved through a small number of individuals, a few small groups of investigators, and only a handful of large teams.* The extent of human capital and associated Highly Qualified Personnel (HQP) dedicated to prostate cancer research in Australia is very low for a developed country of our population and with a generally substantial long term investment in research. It is also low compared to the resources working on breast and colon cancer. This discrepancy was highlighted in 2013 with only three National Health and Medical Research Council (NHMRC) project grants awarded to prostate cancer out of more than 3000 applications and 1100 funded grants. Compared to other nations, normalised for our population, *we punch well below our weight in prostate cancer, and comparatively between disease focused disciplines in Australia we are under achievers.*



Professor Gail Risbridger (left)
and Dr Renea Taylor (right),
Prostate & Breast Cancer
Research Program,
Monash University

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Data collected from funded applications through PCFA's National Research Program show that out of 70 completed grants, six grants have reported a US collaborator (9%) and only 3 grants (5%) are working in collaboration with investigators in other countries (Canada, UK and NZ). *PCFA's Research program has supported truly collaborative small grants (to the value of \$600K) only through a partnership with Cancer Australia.* Movember has recently launched large scale collaborative programs with multi-national participation on given topics. This has given Australian researchers the opportunity to collaborate in the nation and across the globe. *Shortcoming:* Australia struggles in capacity to contribute on par with the more well developed international prostate cancer research teams.

Australia's challenges in prostate cancer are NOT: the tyranny of distance; the lack of acceptance of the importance of the disease in which we study; our research infrastructure; the quality of training of our human capital. Our solutions lie within system-wide changes to the way our research community interacts and how it is supported to achieve greater goals.

While the challenges facing the prostate cancer community are multi-factorial, there are important areas that can be improved with strategic program development targeting the solutions to such challenges. *Firstly* we must be honest about the depth and nature of the challenges. The prostate cancer community, while having some overlapping collaborative networks, largely operates independently and competitively with one another. Many of our institutions and national funding systems largely reinforce and reward individual efforts at the expense of supporting and recognizing the value of collaboration. Some initiatives have tried to bring together researchers' activities, however a fractious nature remains that is detrimental to the potential of unity and synergy of research outcomes that could be achieved through true collaboration, as opposed to cheque book collaboration of sharing funds but nothing more.

In order to improve outcomes in prostate cancer research in Australia, *we need to build capacity* and use that capacity more effectively through shared skill

sets, translating research through relevant disciplines progressively, and working together to improve prostate cancer management for the Australian men suffering from this disease. *The common plank that bonds these aspirations is collaboration.*

A suggested mechanism for fostering new collaborations and strengthening these existing collaborative networks may be to establish *Large Scale Team Program Grants that require a national collaborative effort.* These could be focused around a particular research question or theme that addresses a key and current issue in prostate cancer management in each round and have requirements that they involve investigators Australia-wide, both those established in the field (who should be leading the research given they would have the disease-specific knowledge and prostate cancer track record) and those with strong expertise in their niche field that will add value and provide an innovative edge to the themed program of activity. For instance, thematic areas on key clinical issues such as predisposition and prevention, diagnostic and prognostic biomarkers that discriminate benign prostatic disease from cancer, aggressive from slow growing disease and metastatic phenotypes, and the new, hopefully less invasive, therapeutic approaches that should flow from these endeavours. Phase 1 and Phase 2 clinical trials to confirm their efficacy should be an important component of any such program of activity. These activities need to be underpinned by state of the art high throughput discovery instrumentation in the genetic, genomics and proteomics fields, advanced imaging approaches (both at the molecular and preclinical and clinical levels), preclinical models that better reflect the tumour microenvironment both *in vitro* and *in vivo* as well as high quality annotated clinical samples and the trained high quality personnel to perform these tasks along with bioinformaticians to process the data into meaningful outcomes.

These endeavours are costly and in a small continent like Australia require collaborative networks to maximise the research output which is otherwise dispersed and has reduced impact.

These grants would also need to be well funded if they are to include many investigators and over a reasonable time frame (five years) to ensure maximum benefit and impact which may provide a challenge to the PCFA Funding Scheme. Multidisciplinary approaches that involve basic and pre-clinical scientists, clinicians, nurses, psycho-social counsellors and health economists should also be considered although it may be unlikely that all these disciplines could be accommodated in any one program of activity at a given time.

The essence of multi-disciplinarity should be a core consideration.

Such programs will aim to fund on the basis of excellence, novelty and impact. Preference will be given to teams that have already shown the ability to collaborate productively. Clear research priority and agenda, clear criteria (i.e. demonstration of short, medium and long term impact and benefit to men living with the disease) and milestones, will be set in consultation with the research community.

ENABLE SUPPORT TOWARDS CLINICAL TRIALS IN AUSTRALIA IN ORDER TO DIRECTLY BENEFIT MEN LIVING WITH PROSTATE CANCER TODAY

Australia has robust networks of clinician-investigators committed to performing the highest quality clinical research, based on the best science. Australia also has a remarkable record of organizing, recruiting and completing large clinical trials, in a range of disease entities. This success is reflected in the thirteen cooperative clinical trials groups currently supported by Cancer Australia, as well as several other trial consortia. These groups ensure that strong inter-professional relationships are fostered and training and mentorship opportunities are provided for junior researchers; an investment for the future. These networks bring researchers together in the context of well-established infrastructure and ensure that sites can be nimble in responding to opportunities as they arise. *Australian patients for the most part are willing to participate in research and also to advocate for it, as borne out by our excellent track record for performing prostate cancer studies.* However, the system has imperfections

which largely relate to funding and resources. Industry-sponsored studies in Australia are reducing in number and funding, with secondary implications for the maintenance of the clinical research infrastructure of many institutions. This compromises vital yet underfunded investigator-initiated research. Currently the latter is funded primarily through competitive grants, such as the NHMRC project grant system or co-funding arrangements between NHMRC and partners such as Cancer Australia, PCFA, Cancer Councils and other organisations. NHMRC grants provide the largest funding amounts, and while processes exist for review of clinical trials due to their size and expense, these grants rarely cover all costs. Their limitation to five years of funding (and an added bias against ongoing funding application success) means that outcomes relevant to prostate cancer studies are not usually achievable within the funded timeframe.

Clinical trials must also compete with all other non-clinical research proposals in an increasingly challenging environment of research funding. The co-funded priority-driven research grants are subject to the same stringent review processes but have the advantage of providing a pool of funds specific for that area of research. PCFA currently shares such a scheme with Cancer Australia to support prostate cancer research and for grants commencing in 2013 has taken the welcome stand of prioritising clinical trials above other types of prostate cancer research. Unfortunately, *the funding duration and level presently excludes all but the smallest of clinical trials*, or alternatively will enforce a culture of scientific compromise.

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Australians can be justly proud of their record in clinical research but as a result of shortage of funding this is now under serious threat. It is time to ensure that clinical trials deemed suitable for funding receive support, to ensure that Australian science has an opportunity to be translated into clinical benefits. Several initiatives are needed urgently:

- *Dedicated funding for investigator-initiated clinical trials*, with stringent review by appropriate experts. Resources earmarked for such purposes could be redirected back to the general pool if trials of insufficient quality are not available.
- *Adequate resourcing of clinical trials*, including support for long term follow-up, data collection and analysis.

ENSURE THAT AUSTRALIAN PROSTATE CANCER RESEARCH TALENT DOES NOT FALL THROUGH THE CRACKS OF ACADEMIA AND THAT THE FUTURE OF PROSTATE CANCER RESEARCH IN AUSTRALIA REMAINS SECURE

Basic science

Research oriented toward making basic discoveries in cancer biology must be supported, even if there is a significant lag period between discovery and translation, and even if some of the work fails to be translated (because it may turn out to be useful in the future). *Basic research forms the discovery bank for translational research projects; without basic research this bank will be rapidly exhausted.*

It is essential that we continue to train young, promising research scientists in order to build and expand the prostate cancer research workforce. It is essential to realise the benefits of future research, because *without a constant supply of well trained and capable investigators, productivity, as evident by high quality, peer reviewed research will decline*, leading to a detrimental and significant impact on health care delivery in this country.

Whilst no formal studies have been conducted to track the career progress of PhD graduates, it is a growing trend that fewer doctoral graduates remain in the research-active positions. Other graduates have pursued careers in industry, project management, commercialisation and other non-science related positions. Most are required to complete further studies of MBA or equivalent to be employed in these sectors. There are several barriers that underpin this trend. *Firstly*, we have experienced a generational change in attitudes to careers, where young people are not willing to accept the modest salaries and profound lack of job security that comes with a research career. It is still the case that most staff are employed on 12-month contracts. *Secondly*, the competition for research funding is extreme, such that few people manage to establish and maintain a successful career in research.

Data from the previous six years of funding (NHMRC statistics 2006 – 2011) highlights several gaps in NHMRC funding, particularly for early and mid-career scientists. During this time, the NHMRC supported 203 early career fellows, allowing them to initiate a career in research following the completion of their PhD, including 4 years of training in a supportive institution. However, there were only 83 mid-career positions awarded for researchers with up to 12 year post-doctoral experience (a reduction of 60% of the early career applicant pool). These data highlight a critical gap in funding for the 120 researchers who fail to make the transition from early to mid-career stages. Even more frightening is the fact that the average age of which researchers enter the NHMRC fellowship scheme, which recognises established researchers, is at age 47 years, when people leaving the mid-career stage are usually around 35 years old. There is a gap of over 10 years with inadequate funding.

Collectively, these gaps in funding, and difficult work conditions severely hinder our ability as a country to attract and retain the brightest minds to research and innovation in health and medical research.

This is *a systemic problem in the industry, which needs urgent attention*. More importantly, the percentage of researchers who conduct cancer research are a minor population of the applicants who are focused on all aspects of health and medical research. Of those, even fewer work directly on prostate cancer, with most focusing on other cancers such as breast, melanoma or leukemia.

Clinical science

A clinician scientist, is typically an individual who holds both, a medical degree (MD/MBBS) and a higher degree (PhD or Masters degree), although some successful clinician scientists have not had advanced degrees (e.g. the Nobel Laureates Michael Bishop and Harold Varmus). These individuals often also have specialist training through the colleges such as The Royal Australasian College of Physicians. *The value of a clinician-scientist lies in their capacity to bridge the gap between the clinic and the laboratory; to identify the key clinical questions and apply translational research to address them, as well as to guide the translation of basic research into clinical practice.*

Internationally the number of clinician scientists is dwindling, for a multiplicity of reasons including issues around salaries and grants, rigid medical career structures and insufficient institutional support. In the period 1997-2002 in the US, 27.5% of NIH awards were to MDs, however, the outcomes were less favourable for clinical research compared to non-clinical research. More recent data, has demonstrated that the rate of NIH RO1 awards (equivalent to NHMRC Project Grants) (translational research grants) among physician-investigators was stable over a 40 year period (1964-2004). However, there is a high attrition of clinician-investigators from the grant system especially they are not awarded an initial RO1 grant. Through PCFA's Research Program, over the last five years, 19% of principal investigators on successful grants have been physician-investigators, but only half have MBBS/PhD qualifications. Similarly, only 24% of co-investigators are clinicians (13% MBBS/PhD).

The recent McKeon report (February 2013; www.mckeonreview.org.au) has identified "The current system does not adequately facilitate, incentivise or support research by the clinical workforce. Research is rarely financially rewarding for health professionals, who face increasing pressure to deliver clinical services which reduces time available for research. Protected research time is required to ensure the best clinician researchers remain active in research." The change in the health funding model based on activity based funding now *separates* clinical activity from research and educational activity, making the employment of clinician-scientists within the public/academic hospital environment more difficult and less attractive for local health districts. There are funding opportunities for clinicians 2-7 years post-doctoral, but rarely is funding available in the immediate post-doctoral period. Many clinician-scientists leave research due to the pressures of clinical practice and economic pressures which push them towards the greater financial rewards of clinical practice. Furthermore, clinician-scientists, who pursue their research after their PhD, are often seen as uncompetitive by funding bodies as assessment of track record does not fully take into account the clinical load. As part-time researchers, clinician scientists cannot compete with full-time researchers with regard to number of publications.

SEEK AND SUPPORT INNOVATIVE IDEAS IN PROSTATE CANCER RESEARCH

One of the main criteria of funding through government funding schemes in Australia is feasibility of the proposed project. This requires that researchers conduct most of the work to obtain preliminary data that warrant success of the proposed work at the time of submission, prior to allocation of funding. It is therefore difficult and often impossible for creative scientists to obtain funding for high risk/high return ideas. These ideas can be brought in the field by young or established prostate cancer investigators or senior investigators that currently work in other cancer streams. PCFA's Research Programs aim to identify and fund innovative research ideas that could potentially provide breakthroughs in the field, from prevention to treatment and survivorship. The award will fund such

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innovative ideas when submitted by prostate cancer investigators alone or non-prostate cancer researchers that are collaborating with an established prostate cancer researcher.

ENABLING AND SUSTAINING PROSTATE CANCER RESEARCH NATIONAL NETWORKS IN AUSTRALIA

APCB

One existing network since 2005 is the Australian Prostate Cancer BioResource (APCB) which was initiated by four groups in Brisbane, Sydney, Melbourne and Adelaide who were already performing collaborative research but recognised a need for high quality clinical samples to provide a more translational focus to their research. The APCB has now grown with support from the PCFA and NHMRC to provide a service to all prostate cancer researchers Australia wide. The shortcomings are the lack of support of collaborative networks to use the banked materials optimally, lack of integration with other long standing banking efforts at other institutions, and incomplete clinical follow-up on the subjects. As well, there is concern the APCB will not be supported further in its current form due to changes to NHMRC Establishment grants and biobanking in general.

ANZUP

The Australian and New Zealand Urological and Prostate Cancer Clinical Trials Group (ANZUP), as mentioned earlier, is another recent example of a network that has been established to help initiate more clinical trials for prostate cancer patients in Australia, an area that is sorely lacking. Unfortunately, this initiative may wane for some time unless we can more quickly underpin it with investigator-led Phase 1 and Phase 2 clinical trials of new drug targets or concepts from our own national discovery programs. Reliance on being a feeder into international programs may not be a viable alternative as ANZUP does not support industry sponsored trials, whereas large Industry Pharmaceutical trials being conducted in Australia in prostate cancer do not generally intersect with the prostate cancer research community. A shortcoming of prostate cancer management in advanced disease is that Australia has been slow to uptake the use of medical oncology

agents, which is the area of greatest growth and advancements in prostate research internationally. Our nation needs better collaborative integration of medical specialities treating prostate cancer to more effectively and efficiencies derive benefit from new agents developed overseas or here in Australia.

International Networks in Prostate Cancer

As a community we are more aligned in the strength that we derive from international collaboration. Overall, current benefit to individuals and enthusiasm to collaborate are through international initiatives.

Australian-Canadian Prostate Cancer Research Alliance

More than 230 clinicians and scientists in prostate cancer have joined this network. It has facilitated numerous collaborations, many instigated from its annual meeting and many directly supported with small seed funds. This Alliance's funding will end in 12 months, and while its website and core operation will be maintained as best as possible the incentive stimulation funding will not be maintained.

PRostate cancer AssoCiation To Investigate Cancer associated ALterations in the genome (PRACTICAL)

Excellent outcomes have been derived from this UK-led international genotyping consortium to include Australian efforts in the collaboration. Shortcoming: While these efforts boost collaboration with individuals in Australia with research teams overseas, the nation does not typically have added benefit in building collaborative capacity.

Large Teams that exist in prostate cancer research in Australia

APCRC-Q

The Australian Prostate Cancer Research Centre-Queensland is one of two national dedicated prostate cancer research centres established by the Commonwealth in 2008 with a five year award. The APCRC-Q is based on a collaborative, trans-disciplinary team model that currently supports 65 investigators across the translational spectrum. This large team works in a fluidly integrated way to achieve outcomes and collaborates broadly with other investigators across the nation and internationally. Shortcoming: like other

team research groups, lack of collaborative and stable funding for large scale programmatic research and core support of trans-disciplinary team.

APCRC-Vic

The APCRC-Vic, the first of two dedicated centres created in 2008 with its 'sister' centre in Queensland, likewise seeks further sustainability. APCRC-Vic has recently initiated and largely driven a large scale bid for a Cooperative Research Centre in Prostate Cancer, which unfortunately was unsuccessful. Had this effort been funded, it might have supported a number of key groups in prostate cancer nationally, focused on genomics, drug targeting in a precision medicine approach, and online support for prostate cancer patients across their journey. Shortcoming: there are several large active prostate cancer groups in Victoria and improvement of their alignment and collaboration would be beneficial.

CaPTive

A Victorian State initiative through the Victorian Cancer Agency (VCA - www.victoriancanceragency.org.au/), sought to create a collaborative network of prostate cancer research across the state in a highly inclusive manner. This is in early stages of development in the state, but the intention is well-meaning and seeks to achieve collaborative gain from the State's diverse talent. The evidence to date - after about a year of funding - is that collaboration is good and milestones are being met.

Think-tanks to set a priority agenda and promote collaboration

Expert advice in particular and consultation with major stakeholders are essential to set the prostate cancer research agenda and advise future directions in prostate cancer research nationally.

The program will aim to hold themed "think tanks" where multidisciplinary researchers can come together for 1-2 days to workshop innovative approaches or simply to work out the logistics of forming a collaborative network or themed program of activity. These might also form the basis of, or be a pre-requisite for, a program grant application.

In essence, a combination of collaborative networks, "think tanks" and themed programs of multidisciplinary research addressing core questions of major clinical relevance should generate research outcomes with greater impact on the clinical management of prostate cancer and be of major benefit to the Australian community.

CONCLUSION

We need to ensure that the prostate cancer research ecosystem supports collaborative efforts, through rewards and recognition of collaborative outcomes, removal of barriers to collaborations (complex agreements, IP, institutional overheads arguments, etc.), as well as put in place incentives such as small scale seed funding and discussion and forums that provide the opportunity to learn from what we each have to offer and new endeavours that could be undertaken collectively.

If Australia wants to compete with other prostate cancer research efforts internationally, we need to work together, supported by innovative and purpose-designed programs, from supporting large teams to sustaining and enriching the prostate cancer research workforce. The major benefit secured through collaboration will hasten and heighten our collective efforts to significantly contribute to the global fight on prostate cancer. This endeavour will move us from the old paradigm of publish or perish, to the transformative future underpinned by *collaborate or collapse*.

PCFA'S RESEARCH PROGRAM CATEGORIES 2013-2017

In its quest to fulfil its mission, goals and objectives, PCFA's Research Program will support research under the following categories:

TEAM AWARDS

Aim

To develop a new collaborative scheme for major national collaborative grants that through collaboration and translation would accelerate the pace of discovery and impact of translational research to the community.

Award definition

The Team Award will support a competitive, multi-state, multidisciplinary, translational research **program** in prostate cancer which has one or more specific major objectives. A research program is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project.

We **define** program as a set of projects that involves the organised efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective.

Each research project shall be under the leadership of an established investigator, and the overall Principal Investigator must be a very senior investigator with a track record of collaboration and project management. *Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort.* These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e. a system of research activities and projects directed toward a well-defined research program goal.

The grant will provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort.

Criteria

The Team Award will specifically fund outcome-focused, translational prostate cancer research in a high priority area the results of which are likely to provide relatively immediate benefit to patients (i.e. relating to prevention, diagnosis and treatment of prostate cancer).

What would a collaborative team look like?

These grants will provide support for teams of *high calibre* researchers that may incorporate:

- National and international senior prostate cancer research leaders with proven track record in the field
- National and international senior leaders in other research disciplines and cancer streams that bring specific innovation and value to the team and project as a whole.
- Young investigators and mid-career scientists
- Clinicians (including urologists, oncologists, radiation oncology specialists and pathologists)
- Consumers

Funding

Total funding of \$5M over three years will be provided to the most competitive and significant program every other year*. As specified earlier in this document, the scheme will achieve its aim of providing flexible, substantial funding for leading research teams, as an alternative to the holding of multiple project grants.

Budgets will be inclusive of:

- Salaries for mid-career, young investigators (basic and clinical sciences) and laboratory research assistants (NHMRC scales apply). **Note:** It is expected that the principal investigator has salary support from NHMRC or other sources.
- PhD scholarships and stipends for student exchange nationally and internationally (equivalent to NHMRC stipends)
- Consumables (including reagents, data collection and analysis)
- Administrative support
- Think Tanks

It is a condition of the award that the principal investigators commit no less than 20% FTE to the program.

Infrastructure support of up to \$1M will be provided to the administering institution by the government within the first year of the award as PCFA's Research program is listed in the Competitive Grants Register (DIISR).

Reporting

Objectives, timelines and milestones of the program are to be submitted to PCFA at the time of application for funding.

It is a requirement of the acceptance of the award that Team Leaders organise monthly team meetings to discuss progress and new directions of research and submit progress reports to PCFA on a six monthly basis.

Research progress will be expert reviewed. Feedback will be provided in writing to the principal investigators within four weeks of submission.

CLINICAL TRIALS AWARDS

Aim

To *accelerate* the *pace of discovery* by funding investigator-driven small-to-medium sized clinical trials that are focused on:

- Discovery and validation of novel molecular targets for chemotherapy of locally-invasive or metastatic prostate cancer, including androgen-independent cancers;
- New, non-invasive tests to detect prostate cancer, and/or to determine whether a patient's cancer is curable with radiation therapy or surgery;
- New biomarkers that predict the future clinical course of prostate cancer and/or the response to future chemotherapy and new treatment strategies for prostate cancer, especially locally-invasive or metastatic cancers.

The *objective* of these grants, in partnership with Cancer Australia, is to *enhance* Australia's capacity to conduct *high-quality, scientifically valid and clinically relevant* prostate cancer clinical trials. These grants might directly benefit men with prostate cancer via their participation in such clinical trials.

It is anticipated that this funding will:

- Increase participation in clinical trials by people affected by prostate cancer and clinical professionals;
- Increase the number of prostate cancer clinical trials conducted in Australia; and
- Increase the number of clinical sites actively participating in prostate cancer clinical trials.

In achieving these objectives, PCFA and Cancer Australia will support new and existing Multi-site Collaborative National Prostate Cancer Clinical Trials Groups in a way that is efficient, ethical, accountable, transparent and represents value for money.

PCFA'S RESEARCH PROGRAM CATEGORIES 2013-2017

Funding

Up to 200K/year over three years (total of up to 600K over three years, based on assessment of progress) will be offered to the most competitive trials in any given year. Pre-clinical validations of new compounds will NOT be funded via this category.

Funding provided to the multi-site, collaborative national cancer clinical trials groups will be provided to support:

- Salaries of key trials and administrative personnel
- Drug and recruitment cost
- Education and training for trials personnel,
- Data management frameworks, statistical design, analysis and review

Funding will NOT be provided for elements associated with trials such as indemnity and insurance costs, legal costs, bank fees, university overheads, clinical service delivery, or infrastructure for clinical services.

Reporting

PCFA and Cancer Australia intend to provide a common reporting framework by which to measure processes, activities and outcomes. All funded activities will be underpinned by a strong, transparent evaluation and reporting framework. All Multi-site Collaborative National Cancer Clinical Trials Groups will be required to adhere to Cancer Australia Evaluation Framework and Performance Criteria, reporting against identified performance criteria at specified time points.

Funded clinical trial groups are required to comply with the terms and conditions of funding provided by Cancer Australia. Groups must adhere to research plans and demonstrate financial accountability including identifying specifically how the funds received through the program have been spent. Cancer Australia requires annual progress reporting, final reports and a follow up report 18 months upon cessation of funding.

YOUNG INVESTIGATOR AWARDS

YOUNG INVESTIGATOR AWARD (BASIC SCIENCE)

Aim

This funding category has been running for five years of the program and will continue well into the future.

The Young Investigator Award is aimed at funding the brightest young basic science researchers to undertake research into prostate cancer and to support those investigators as they mature toward becoming independent scientists. The candidate must fulfill the following criteria:

- Should have been engaged in research for approximately 5-7, and no more than seven years after receiving their PhD, unless exceptional circumstances exist
- Should have an excellent track record in relation to opportunity and at least an emerging track record in prostate cancer research, as demonstrated by an absolute minimum of one publication in prostate cancer research. Applicants with no prostate cancer research publications will be deemed ineligible
- Demonstrate that they will have access to the facilities needed for the proposed research and will be in a research environment that will support their development in accordance with the aims of this grant.
- Have a mentor who can guide their research and the development of their careers.
- Be an Australian citizen or hold permanent residency in Australia and must be based in Australia for the duration of the grant.

Funding

This award will provide salary support (total funding of up to \$600K, up to \$150K per annum, over a period of four years) (up to \$150,000 per annum for up to four years).

YOUNG INVESTIGATOR AWARD (CLINICAL SCIENCES)

Aim

Through funding of the most talented young clinicians that are committed to prostate cancer research, this award aims to support clinician researchers that have currently completed their PhD and are working as part of an established prostate cancer research program. This category, much like the Young Investigator category for basic scientists, aims to revive and renew the prostate cancer research force and ensure the continuation and the future of medical research in Australia.

The scheme will fund, for the first time, young clinician scientist that aspire to pursue an academic career in research with a focus on prostate cancer in areas of prevention, treatment and survivorship. The **Young Clinician-Scientist Award** is aimed at bridging the gap between the clinic and the laboratory.

It is a requirement of funding that these candidates hold a PhD in research or be in the last year of their PhD. In addition, the candidate must fulfil the following criteria:

- Have a clinical and a scientific mentor can guide their research and the development of their careers
- Work within a research group (i.e. must not be a solo researcher)
- Commit 40% of their time to research
- Be an Australian citizen or hold permanent residency in Australia and must be based in Australia for the duration of the grant.
- Demonstrate that they will have access to the facilities needed for the proposed research and will be in a research environment that will support their development in accordance with the aims of this grant.

Funding

This award will provide salary support (total funding of up to \$600K, up to \$150K per annum, over a period of four years for a clinician based on time spent on direct research activities or for a research assistant that will support the research activities of a clinician scientist.

ENABLING GRANTS

Aim

Whenever possible, Enabling Grants will assist Australian researchers to continue high quality, world-class research thereby strengthening prostate cancer research efforts nationally. It is our goal to establish criteria and processes that, within the limits of the total expenditure of the research program, will allow funding of excellent and necessary facilities and/or activities where there is a clearly demonstrated need.

Funding

A call for submission of enabling grants will be open each year, though these grants will not be part of the structured Research program. Criteria, submission guidelines and review process will be posted on PCFA's website.

PCFA'S RESEARCH PROGRAM CATEGORIES 2013-2017

THINK TANKS

Aim

This funding is aimed at enabling the prostate cancer research community, health professionals, policy makers and the community at large (i.e. men living with prostate cancer and their carers) to synthesise, create and/or communicate ideas that would lead in to the generation of new directions in prostate cancer research nationally.

PCFA encourages submissions from groups of researchers nationally.

Funding

Funding of up to 15K for up to four meetings will be provided twice a year for multidisciplinary, multisite groups to:

- Discuss opportunities for strategic collaborations to address a critical aspect of prostate cancer;
- Encourage integration of new expertise;
- Use these “think-tanks” as a vehicle to plan proposals for PCFA collaborative projects.

Think Tanks might also include one or two key international participants that would increase our exposure and their knowledge of what is going on outside the US/Europe (GR).

Because think tanks can occur at different times during any calendar year, PCFA will not set up specific deadlines for submission of these applications but rather review all applications and fund on merit.

Think Tanks might also include one or two key international participants that would increase our exposure and their knowledge of what is going on outside the US/Europe (GR).

EVALUATION AND PROCESSES

In close consultation with the Research Advisory Committee, our funding partners, the research community and international non-profit entities supporting research in prostate cancer, PCFA will ensure gold standard practices are in place for the submission and assessment of applications for funding as well as the evaluation of the research programs in the short (five years) and longer term (10 years).

Similarly, to enable transfer and more importantly, translation of the generated knowledge through support of the best research, PCFA will develop a strategic knowledge translation plan that will benefit all stakeholders, particularly men with prostate cancer and their families.

RESEARCH
AWARENESS
SUPPORT

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