VICTORIAN COMPREHENSIVE CANCER CENTRE

STRATEGIC RESEARCH PLAN 2017-20

Supported by

VICTORIAN COMPREHENSIVE CANCER CENTRE

VICTORIA State Government

Contents

Preface

The Victorian Comprehensive Cancer Centre (VCCC) envisages a future where more cancers are cured and many cancers can be survived. More rapid translation of the latest in cancer research into improved treatment will enable the VCCC to make a real difference to the lives of patients and their families.

VCCC Vision

The VCCC will save lives through the integration of cancer research, education and clinical care. Through innovation and collaboration, the VCCC partners, in conjunction with others, will drive the next generation of improvements in the prevention, detection and treatment of cancer.

VCCC Mission

The VCCC mission is to more quickly translate the latest research and evidence into improved patient outcomes.

The VCCC alliance (the alliance) of seven tertiary hospitals, two medical research institutes and Australia's top-ranking university complements existing excellence in research and care by fostering and enabling collaboration and coordination. The alliance brings together a critical mass of expertise in cancer research, education and care to drive innovation and more rapid translation of new research and evidence into routine clinical care.

The VCCC Strategic Research Plan 2017–2020 is enabled by a major investment from the Victorian government and direct support from the alliance partners. The plan has been carefully designed to complement the research, education and clinical trial programs of the VCCC's member organisations. The result of an extensive co-design process, it brings together perspectives and counsel from our partners, key external stakeholders and consumers to focus new activity where it can most rapidly advance progress in areas of unmet need.

There is much work to do as we strive to control cancer. Through effective and strategic collaborative programs, bringing together excellent cancer research, best clinical care and high quality education and training, the VCCC will accelerate the journey to better outcomes for Victorian cancer patients.

Professor Grant McArthur

Executive Director, VCCC

Professor Andrew Roberts

Chair, VCCC Strategic Plan Working Group

Executive Summary

The VCCC Strategic Research Plan (2017–2020) is the culmination of nine months of extensive consultation, collaborative planning and co-development work. Through targeted investment of $30 million awarded by the Victorian Government for these purposes, the plan sets out how the VCCC will enhance research capability and capacity, accelerate research translation, and expand clinical trial activity and patient participation, underpinned by education and training and better connectivity. The new initiatives described in the VCCC Strategic Research Plan leverage the ongoing research efforts of all VCCC alliance partners, who collectively spend more than $110 million per annum on cancer research, and build on partnerships across Victoria, Australia and the world.

The VCCC Strategic Research Plan (SRP) has been designed to maximise impact and collaborative gain through prioritising areas of unmet need and work that is beyond the scope of individual organisations working independently. In addition, consumer engagement has been critical to program design, and all programs meet strong expectations around feasibility and international competitiveness. Emphasis has been given to programs of work that could be expanded to benefit the community more broadly in future.

The major outcomes in the next five years will be:

- a greater number of **clinical trials** conducted in a broader range of cancer fields, with growth in the number of patients participating in trials and clinical cancer research
- greater capacity and capability of the **cancer research workforce**
- development of new collaborative programs in **rapidly advancing areas of cancer research**, such as immunotherapy, targeted therapies and precision prevention and tailored screening
- accelerated **translation of research advances** into standard care for patients with cancer

The greatest impacts will be realised in the medium to long term, as advances in research flow into improved outcomes for patients and in the conduct of cancer control.

The SRP contains 19 programs. The plan sets out context and rationale, what each aims to achieve, the new activities being generated, and milestones and measures that will define success for each program, as well as opportunities for leverage and sustainability. Importantly, the 19 programs are highly interconnected with each other; across the VCCC alliance partners *and* with external cancer-related organisations and initiatives (Appendix C).

The VCCC has a well-established governance structure that will support and safeguard implementation of the Strategic Research Plan and provide financial accountability. The progress of programs will be reviewed by the VCCC Cancer Research Advisory Committee (CRAC), in conjunction with other VCCC committees. The plan is designed to have some flexibility and to be able to incorporate significant new areas or opportunities that may emerge during the three years of the plan.

The clinicians, researchers and educators within our partner organisations and consumers who have co-developed the Strategic Research Plan are excited about its potential, are proud to own it and are invested in its success. The VCCC is pleased to present this comprehensive, integrated Strategic Research Plan to the Victorian State Government. We believe it brings together all the necessary ingredients for the VCCC to deliver major advances in cancer research and expansion of clinical trial participation in Victoria that will lead to better patient outcomes.

Context

The VCCC – partnership for success

The Victorian Comprehensive Cancer Centre (VCCC) was established in 2009 as a powerful alliance of ten successful Victorian organisations committed to cancer control.

The VCCC alliance brings together the Peter MacCallum Cancer Centre, Melbourne Health, the University of Melbourne, the Walter and Eliza Hall Institute of Medical Research, the Royal Women's Hospital, the Royal Children's Hospital, Western Health, St Vincent's Hospital Melbourne, Austin Health and the Murdoch Childrens Research Institute.

The VCCC is founded on the NCI Comprehensive Cancer Centre model, in which research excellence is the basis for accelerating the discovery, dissemination and adoption of better ways to prevent, diagnose and treat cancer through the integration of comprehensive programs of cancer research, education and clinical care.

The VCCC's partnership model – and the scope, scale and depth in expertise, knowledge, practice and patient numbers it represents – provides a strong strategic advantage. Collectively, the VCCC alliance is Australia's largest and highest impact cancer research program. 40% of Australia's top 1% most cited cancer papers are authored by at least one VCCC researcher.

To have the greatest possible impact on cancer and enable all Victorians to benefit from the VCCC, evidence-based improvements in cancer control must be implemented across the whole Victorian healthcare system, not just VCCC partner hospitals. The VCCC is actively developing relationships with other cancer-focussed organisations across Victoria, Australia and the world, to complement and enhance expertise, resources, connections and impact. Partnerships and collaborations for each program are listed in Appendix C.

Alignment with Strategic Plan

Developed in 2015, the VCCC's Strategic Plan (2016-20) was designed to deliver three benefits to Victoria: a reduced burden of cancer, a world-class centre of excellence in cancer research and clinical care, and increased investment in biomedical research.

The principles underpinning this included:

- Patient-focused – delivering experiences and outcomes that patients want
- Evidence-based – supported by science
- Excellence and best-practice – benchmarking with the best in the world
- Collaborative and cooperative – working in partnership
- For all Victorians – benefiting the whole community

The VCCC Strategic Plan (2016 -2020) describes six priorities, with the long term goals to:

- Deliver the world's best cancer survival rates and cancer patient experience
- Be recognised as a global centre-of-excellence in all forms of cancer research and in evidence-based cancer care
- Be an international hub for outstanding cancer education and training

The VCCC Strategic Research Plan 2017-2020 has been developed in alignment with the overall strategic plan, and should be read in conjunction with it. It builds on the groundwork established by the first VCCC strategic plan (2010-15).

Leadership

The VCCC employs a distributed leadership model to embed its work within its partner organisations. The VCCC Executive Director, Board, and three advisory committees: the Cancer Consumer Advisory Committee (CCAC), the Cancer Education and Training Advisory Committee (CETAC) and the Cancer Research Advisory Committee (CRAC) have supported this model as a means to grow the collaborative culture across the VCCC.

The Research and Education Lead Program was established in 2015 as the embodiment of this distributed leadership model, working within the tumour stream structure to integrate research and education/training into clinical practice. Leads established in tumour streams and two cancer themes (primary care integration and cancer nursing) are championing system-level collaboration across the VCCC, and acting as thought leaders and ambassadors across the alliance. Their work is detailed in Program 15.

The VCCC has committed to building academic leadership through its Leaders in Cancer Strategy. Under this strategy, academic appointments (13 Chairs or professorial posts and seven fellowships) have been created that have retained, developed, recruited or commenced recruiting research talent in a broad range of fields to build a truly comprehensive cancer program. The Leaders in Cancer Strategy addresses previously-agreed strategic objectives such as developing research capability, increasing the number of clinician scientists and developing, retaining and recruiting the best research talent. These academic positions have been constructed so the appointees can work seamlessly across the University and hospital partners.

Engagement and consultation

As an organisation created to promote collaboration, the development of this Strategic Research Plan was a truly collaborative process. The extensive consultation undertaken by the VCCC since 2009 was consolidated and an engagement plan guided further consultation with key stakeholders.

The SRP was co-designed by the VCCC and a Strategic Research Plan Working Group (SRP WG) that represented VCCC partners and a breadth of expertise in cancer research, education and care. The plan was continually tested as it was developed, with consumers, with early career researchers, and with our partner organisations, including at two forums attended by over 60 people. The co-development process chosen for the SRP has proved to be effective at creating the buy in that will be essential for its successful delivery. The co-design process and acknowledgements are detailed in Appendix A.

Principles for development of the Strategic Research Plan

The VCCC Board agreed five principles to guide the development of the Strategic Research Plan:

1. the draft Strategic Research Plan will align with (and interpret) the direction given in the Funding Agreement that the VCCC is a translational research platform
2. the four agreed themes will be further developed, namely building research capability, translating research into practice and policy, developing the cancer clinical trials program, and a framework for cancer education and training
3. the programs proposed in the VCCC Strategic Research Plan should clearly build on the work already done within the VCCC partnership and on the research plans developed by the VCCC partners
4. the VCCC will not act as a funding body for research, but rather seek to build joint research capability and activities collaboratively with partners and by leveraging funding
5. the Strategic Research Plan will prioritise activities most likely to make the greatest impact on patient outcomes that cannot be easily achieved by individual VCCC partners alone.

The SRP WG developed a set of principles that guided the prioritisation of potential programs and selection of the final 19 that are set out in this document. These principles are outlined in Appendix B.

Strategic Research Plan (2017 -2020) Overview

The SRP is designed to deliver increased research capability, capacity and translation into practice, and increased clinical trial access and participation through seeding new initiatives and developing new models of application, leveraging current activities and building the skilled workforce.

The prioritised programs are intrinsically interconnected, but can be considered in three broad groupings: rapidly advancing areas of research; clinical trials research and translational research enablers.

Within these broad groupings, nineteen programs have been prioritised.

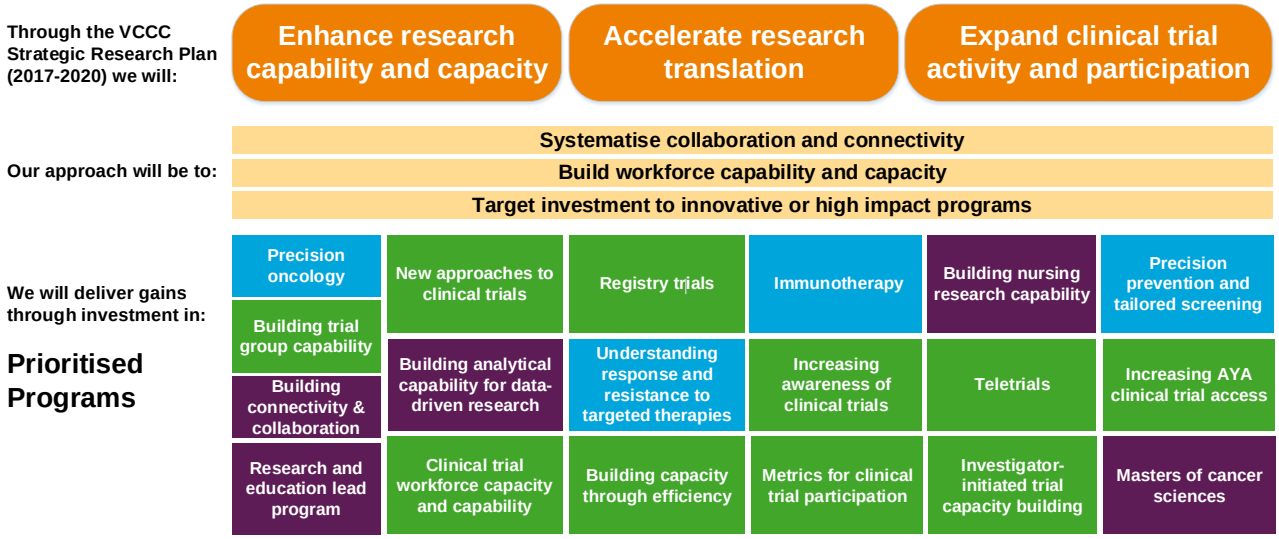


Figure 1. VCCC Strategic Research Plan Overview

Rapidly advancing areas of research

The four programs in this section capitalise on the strengths in cancer biology across the VCCC as well as existing platform technologies and bring these strengths closer to areas of specific need in the clinic. These programs complement VCCC's clinical strengths in early phase trials, imaging and prevention.

These programs aim to make the cutting edge of cancer research ready for application in clinical practice in the short- to medium-term. These four programs are:

- Program 1: Immunotherapy
- Program 2: Precision oncology
- Program 3 Precision Prevention and Tailored Screening
- Program 4: Understanding Response and Resistance to Targeted Therapies

Clinical trials research

Clinical trials drive improvements in cancer care. They also provide conduits for translation of discovery research into routine clinical practice. Clinical trials are a key feature of the comprehensive cancer centre model and central to the rigorous evaluation of proposed new approaches for diagnosing, treating, and preventing cancer. Ten of the SRP programs focus on clinical trials. These will deliver an expanded trial portfolio with an emphasis on building capability in currently underserved areas, increasing access for patients across Victoria, building the skilled workforce and developing key metrics.

The proposed VCCC clinical trial endeavour has been constructed to address current areas of greatest need and the most significant gaps in activity across the VCCC. The investment focusses on the areas where the VCCC has the potential to add the greatest value, while seeking to leverage the efforts of the many organisations already working towards improvements in clinical trials. To deliver significant improvements in clinical trial participation over the next 10 years, all of the components of the system are to be addressed cohesively.

The Clinical Trials Research component of the plan has been organised into five broad areas, each comprising a number of programs.

These five areas are:

Capacity building

- Program 5 Investigator-initiated Trial Capacity Building
- Program 6 Building Capacity through Efficiency

Expanding the trial portfolio

- Program 7 Building Trial Group Capability
- Program 8 New Approaches to Clinical Trials
- Program 9 Registry Trials

Increasing access

- Program 10 Teletrials
- Program 11 Increasing AYA Clinical Trial Access
- Program 12 Increasing Awareness of Clinical Trials

Developing the workforce

- Program 13 Development of Workforce Capacity and Capability

Measurement and impact

- Program 14 Metrics for Clinical Trial Participation

Translational research enablers

These programs build capability and capacity for research and its translation, with an emphasis on filling gaps in leadership, key skill areas, education and team-building. These five programs are:

- Research and Education Lead program
- Building Analytical Capability for Data-driven Research
- Building Nursing Research Capability
- Building Connectivity
- Masters of Cancer Sciences

The 19 programs are detailed individually in the next section. All leverage current investments in infrastructure, people, existing research projects or clinical programs.

Programs of work

Section A: Rapidly advancing areas of research

The four programs in this section capitalise on the strengths in cancer biology across the VCCC as well as existing platform technologies, and bring these strengths closer to areas of specific need in the clinic. These programs are designed to complement VCCC clinical strengths in early phase trials, imaging and prevention. The four programs are:

- Program 1: Immunotherapy
- Program 2: Precision Oncology
- Program 3: Precision Prevention and Tailored Screening
- Program 4: Understanding Response and Resistance to Targeted Therapies

Program 1: Immunotherapy

The VCCC will invest around $1 million in an immunotherapy program so that assays, techniques and platform technologies used in fundamental immunology and tumour immunology research are applied in the clinic more often and more quickly. The program will also help maximise patient benefit from the latest immunotherapies, through access to more clinical trials of immunotherapies.

The key elements of this program are:

- leadership for a new Centre for Immunotherapy.
- support for a VCCC Virtual Translational Immunobiology Laboratory.

Context

The Centre for Immunotherapy on Level 13 of the VCCC building will incorporate 60 laboratory-based scientists plus dry-lab researchers and will work closely with cancer immunology researchers across the VCCC.

Rationale

Immunotherapies are a new class of anti-cancer therapy that have the potential to change the way cancer is treated. Comprehensive cancer centres world-wide are investing in preclinical and clinical research in this field.

The VCCC partners have internationally competitive research programs in fundamental immunology and tumour immunology, as well as growing clinical expertise in the use of new immunotherapies to maximise patient benefit.

The best options for adding value to the VCCC partners' immunotherapy research through VCCC investment were identified as:

- supporting a leadership role (the Director for the Centre for Immunotherapy) whose remit would be to drive activities that maximise collaborative gain. These activities apply research strengths and platform technologies from fundamental immunology and tumour immunology directly to clinical studies and clinical trials of immunotherapies. Prioritised studies will be designed to identify which patients will benefit from different immunotherapeutic agents (alone and in combination with other therapies) and to understand the biology behind these benefits. This role does not currently exist at any of the VCCC partner organisations.
- supporting access to platform technologies currently used by fundamental immunologists and tumour immunologists, so that samples from patients enrolled in clinical trials can be assayed for indicators of treatment efficacy and for biomarkers of response and/or resistance to immunotherapies.

Several other rationales for investment in an immunotherapy program were identified including that:

- development of an integrated immunotherapy program is the most effective way to leverage the investment for the fit out of Level 13 of the VCCC building.
- Australian cancer centres are currently lagging behind other leading western cancer centres in bringing clinical trials of immunotherapies to cancer patients, limiting the access that Australian cancer patients have to new immunotherapies.
- the VCCC partners already have the critical mass, breadth of expertise and reach to provide national and international leadership in all facets of cancer immunology research and the treatment of cancer patients using immunotherapies – however activities could benefit from coordinated collaboration.

- this critical mass and expertise will make a coordinated VCCC immunotherapy program competitive for new funding via peer-reviewed grants, philanthropy and industry grants, particularly for investigator-initiated clinical trials of new immunotherapies across the VCCC.
- an integrated bedside to bench research program will enable clinicians and researchers to better address why only some patients treated with immunotherapies achieve durable responses.

Leverage and synergies

- The Ian Potter Centre for New Cancer Treatments on Level 13 of the VCCC building.
- Existing immunotherapy programs within the VCCC alliance (Peter Mac, UoM, Melbourne Health and Austin Health/ONJCRI).
- High impact, laboratory-based immunology research at a number of VCCC partner organisations.
- A successful model for a virtual multispectral immunohistochemistry platform established at ONJCRI and Peter Mac.

Connectivity with other priority programs

- Precision Oncology program: DNA- and RNA-based genomics capability including immunogenomics.
- Understanding Response and Resistance to Targeted Therapies program: infrastructure and platform technologies for biomarker assays at VCCC partner organisations.
- Clinical trial programs.

Goals/desired outcomes

More patients, with more types of cancer, having the opportunity to benefit from immunotherapies through:

- Better integration of existing laboratory and clinical research expertise in immune-based therapies so that assays, techniques and platform technologies from fundamental immunology and tumour immunology research are used to a greater extent in clinical trials and clinical research.
- Greater collaboration between laboratory-based immunology researchers and cancer clinicians across the VCCC, leading to:
    - More clinical trials of novel immunotherapies, especially investigator-initiated trials.
    - New trials that focus on the targeted use of immunotherapies, informed by research in, for example, immunogenomics and biomarkers of response.
    - Acceleration of the trial and use of novel biomarkers of response and resistance to immunotherapies that are poised for the proof-of-concept stage of research.

Timelines

An international search for the Director for the Centre for Immunotherapy has already commenced. An appointment is expected to be made by Q2 2018. Depending on the timeframe for relocation of the appointee, work to build a collaborative and integrated translational research program will occur in Q3-4 2018, with the Director expected to commence at or before Q1 2019.

To commence some activity in this program prior to the commencement of the Director, a scientist/laboratory manager will be appointed in mid-2018 to do the preparatory work so that the Virtual Translational Immunobiology Laboratory can begin its functions when the Centre for Immunotherapy on Level 13 of the VCCC opens, which is expected in June 2018.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Centre for Immunotherapy	Q4 2017 (search) Q1 2019 (research program)												
Virtual Translational Immunobiology Laboratory	Q2 2018 (development) Q2-Q3 2018 (operation)												

Activities

Activities that occur under the leadership of the Director of the Centre for Immunotherapy will not be able to be detailed until the successful candidate is appointed. Nevertheless, the KPIs for the appointee will drive expected activities including:

- collaborative clinical research projects between fundamental and tumour immunologists and cancer clinicians that align with the goals and desired outcomes for this program.
- setting up an integrated immunotherapy clinical trial program at all VCCC clinical sites.

Activities to be conducted by the scientist/laboratory manager of the Virtual Translational Immunobiology Laboratory will include:

- identification of which existing platform technologies are to be included in the Virtual Translational Immunobiology Laboratory.
- agreements on processes and costs to access the agreed platforms, and the resources and personnel at VCCC partners that will contribute and/or be subsidised.
- quality assurance and accreditation, if required, of agreed assays for clinical research.
- co-ordination of patient sample collection, transport and storage.
- conducting some of the assays for clinical trial and clinical research samples.

Milestones

Milestones have been outlined for the initiation of this program and the first 6 months after the opening of the Centre for Immunotherapy. Once the key personnel are appointed and processes agreed, milestones for 2019-2020 will be developed that will focus on assaying samples from patients enrolled in immunotherapy clinical trials and initiation of new immunotherapy clinical trials.

Interim measures of success will be evaluated after 12 months of operation of the Virtual Translational Immunobiology Laboratory, noting the linkage of these milestones to the number of immunotherapy clinical trials being conducted across VCCC partner hospitals.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Agreement on reporting lines and roles and responsibilities for the Director of the new Centre for Immunotherapy, an agreed position description and advertisement of the role	Q4 2017- Q1 2018
Appointment of the Director of the Centre for Immunotherapy	Q3 2018- Q1 2019
Appointment of a scientist/laboratory manager for the Virtual Translational Immunobiology Laboratory	Q3 2018
Processes for sample co-ordination and access to platform assays developed and agreed	Q4 2018
Criteria for subsidisation of assays associated with clinical trials developed and agreed	Q4 2018
Evaluation of interim measures of success	Q4 2019

Measures of Success

Because the Centre for Immunotherapy element of this program involves setting up a new translational research program, measures of success that reflect the goals/ desired outcomes are unlikely to change significantly in the short- medium term. Measures of success for which change will be seen in the longer term include:

- measures of research impact.
- measures of research income and funding leveraged.
- impact of immunotherapy clinical trials.

Therefore, interim measures of success will monitor both progress towards the goals/ desired outcomes and early successes, allowing for the time for appointment of the Director, known productivity lags for new appointments and time lags for outcomes for new research programs. These include:

- number of immunotherapy-related collaborative projects initiated.
- number of immunotherapy-related collaborative grants applied for.
- number of immunotherapy clinical trials.

The measures of success for the Virtual Translational Immunobiology Laboratory element of this program will be assessable in the medium to long term. These will include:

- number of samples assayed using one of the platform technologies included within the virtual laboratory.
- number of clinical trial protocols developed that include immune biomarker assays.
- number of clinical trial samples assayed by the virtual laboratory.
- number of clinical trials utilising biomarker assays provided by the virtual laboratory.
- number of clinical research projects utilising biomarker assays provided by the virtual laboratory.

Measures of success for which change will be seen in the longer term will align to the goals of the virtual laboratory and will include publication and clinical impact of research that utilises the services of the virtual laboratory.

Budget

	Type/Volume	Budgeted amount	Program element	Alliance member
Labour Costs				
Director salary	0.2 FTE	$300,000	Director- Centre for Immunotherapy	Joint appointment Peter Mac, UoM & VCCC
Scientist/ laboratory manager salary	Postdoctoral scientist 1 FTE	$300,000	Virtual Translational Immunobiology Laboratory	Joint appointment- Peter Mac and UoM
On-costs				
Director salary	N/A	$60,000		
Scientist/ laboratory manager salary	20%	$60,000		
Consultancies				
Direct Research Costs				

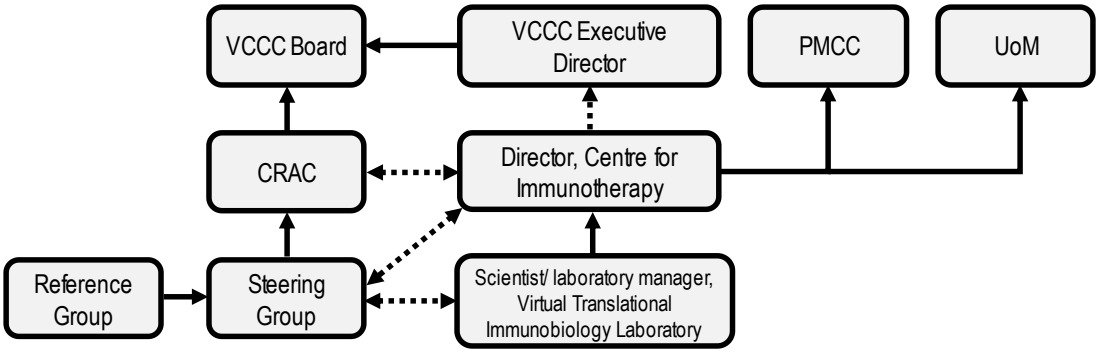
Subsidies for assays in the Virtual Translational Immunobiology Laboratory		$300,000	Virtual Translational Immunobiology Laboratory	Centre for Immunotherapy
Enabling Facility Costs				
Other Costs				
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000		
Total		**$1,065,000**		

Governance

The immunotherapy program will have a Steering Group, with appropriate scientific expertise, that reports to the VCCC Cancer Research Advisory Committee (CRAC). One member of the Steering Group will be a CRAC member. The Steering Group will also act as an advisory group that supports the new Director. Decisions around access to platform assays and criteria for subsidisation of assays associated with clinical trials will be overseen by a larger Reference Group that will be both representative of the 10 VCCC partner organisations and have the required expertise. At least one member of the Reference Group will also sit on the Steering Group.

The Director will have a joint appointment at UoM and Peter Mac with direct reporting lines to both these organisations and an indirect reporting line to the Executive Director of the VCCC. The Director will have the option to become a member of CRAC.

The scientist/laboratory manager of the Virtual Translational Immunobiology Laboratory will report to the Director and be jointly employed by Peter Mac and UoM or through one of these partners as agreed. As an interim measure until the Director is appointed, the scientist/laboratory manager will report to the Head of Research Development at the VCCC and through this channel report to CRAC. The scientist/ laboratory manager will also be supported by the Steering Group until the Director commences.



Opportunities to enhance sustainability

The high impact translational immunotherapy research program under the leadership of the new Director will be competitive for new funding via peer-reviewed grants, philanthropy and industry grants, particularly for investigator-initiated clinical trials across the VCCC.

Ongoing investment in immunology, tumour immunology and immunotherapy research programs by UoM, Peter Mac and other VCCC partners as suits their research portfolios.

Cost-recovery for assays conducted by the Virtual Translational Immunobiology Laboratory in the longer term from commercial trial budgets.

Program 2: Precision Oncology

The VCCC will invest around $1.5m in genomic pathology to move towards the integration of patients' molecular data into routine clinical decision making, building on the preliminary success of the VCCC Molecular Tumour Board, established in 2013.

The key elements of this program are:

- a system to request genomic assays for those patients who are most likely to benefit.
- standardised interpretation and reporting of genomic pathology data.
- integration of the precision oncology program with molecularly-directed clinical trials, particularly n=1 trials via the New Approaches to Clinical Trials program (Program 7).

Context

The VCCC Molecular Tumour Board assesses genomic information alongside other patient data and provides multi-disciplinary opinions on the clinical implications of molecular pathology results for referred patients.

Rationale

The principle of precision oncology is to 'give the right drug to the right patient at the right time' by using genomic profiling of the tumour to guide treatment. However, while next-generation genome sequencing technologies are increasingly used in clinical research and to select patients for clinical trials, they are not yet well integrated into routine clinical practice.

Within the VCCC partners, next-generation sequencing of comprehensive cancer genomic panels is already being used in in a clinical setting and to select patients for clinical trials of targeted therapies. In addition, the NovaGen Platform for whole genome sequencing, which can provide additional insights into chromosomal rearrangements, mutational signatures, mutation burden, broader coverage of germline predisposition and the ability to detect genomic catastrophes as well as point mutations, has been recently established at the University of Melbourne Centre for Cancer Research.

The areas where the VCCC could add most value to partners' investments in next-generation genomic sequencing were identified as:

- integration of genomic pathology, computational oncology and clinical care into a single process which will include the existing Molecular Tumour Board.
- providing extra resources for curation of genomic data, which is the rate limiting step for providing genomic information about a patient's tumour in a clinically useful timeframe.

Several other rationales for investment in a precision oncology program were identified, including that:

- the VCCC is the only comprehensive cancer centre in Australia with sufficient size and scope to effectively co-ordinate genomics, pathology, oncology and surgery on the scale, and in the time-frame, required for an international-standard genomic pathology program. However, the VCCC is currently well behind its international comprehensive cancer centre peers in its use of genomic pathology.
- In the current era of genomic medicine, to provide best care to patients (and particularly in the case of challenging tumours), clinicians need to know:
    - the likely root cause of their patient's tumour.
    - whether there are founding-drivers in the tumour that are targetable.
    - whether there is evidence of druggable phenotypes, like hyper-mutation.
    - whether DNA damage deficiency and genomic instability are present.
    - whether the tissue of origin matches the somatic mutation profile.

- whether there is any evidence of pathogenic germline defects.

Leverage and Synergies

- The Melbourne Genomics Health Alliance infrastructure.
- The iPredict Program, supported by both the Melbourne Genomics Health Alliance and the Australian Genomics Health Alliance. This uses comprehensive cancer genomic panel assays already established at Peter MacCallum Cancer Centre to match patients to clinical trials.
- Deep whole genome sequencing and whole transcriptome sequencing, using NovaSeq sequencing technology, currently being established in the UoM Centre for Cancer Research.
- Existing expertise in cancer genome interpretation.
- Internationally benchmarked approaches to genomic cancer pathology from the International Cancer Genome Consortium (ICGC) and The Cancer Genome Atlas and direct links with the ICGC through the UoM Centre for Cancer Research.
- Existing expertise and capacity in early Phase clinical trials of novel targeted agents across the VCCC.

Connectivity with other priority programs

- New Approaches to Clinical Trials program: clinical trials requiring molecular stratification such as first-in-human trials and novel trial designs such as n=1 trials.
- Research and Education Lead program: contribution of mapped networks of expertise in tumour streams to collective decision making.
- Immunotherapy and Understanding Response and Resistance to Targeted Therapies programs: application of genomics platforms for understanding the basis of response and resistance to immunotherapies and targeted therapies.

Goals/desired outcomes

- Greater consensus on the optimal application of different genomic pathology assays.
- For patients who are most likely to benefit, genomic profiling of their tumour to be available in a clinically useful timeframe.
- More cancer clinicians upskilled in the use and interpretation of genomic pathology.

Timelines

This program provides support for curation and reporting of genomic data from the beginning of 2018 for a period of two years, after which time it is expected that that this activity will be self-supporting.

The system for requesting genomic tests will take approximately 6 months to develop (from Q4 2017), and will therefore begin in mid-2018. This system and the Molecular Tumour Board will continue to be supported until the end of the current funding agreement.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Curation of genomic pathology data	Q4 2017 (appointment & training) Q2 2018 (Reporting to MTB)												
System to request genomic assays	Q4 2017 (development) Q3 2018 (operation)												

Activities

Activities that will lead to standardised interpretation and reporting of genomic pathology data will include:

- appointment and training of two genomic curation scientists. Curators will be employed by the Molecular Pathology Laboratory at Peter Mac and the University of Melbourne Centre for Cancer Research and will work across both laboratories to maximise collaborative gain.
- appointment of a part time medical oncologist to provide clinical input into reporting of genomic pathology data to referring clinicians and to the Molecular Tumour Board.
- curation of genomic data and generating standardised reports by the appointed curators, in consultation with the staff medical oncologist, for the treating clinician and/or for multi-disciplinary consideration at the Molecular Tumour Board depending on the complexity of the case.
- refinement of the operations of the Molecular Tumour Board to align with new referral/request systems and standardised reporting of genomic information.

The system to request genomic assays for patients most likely to benefit will need to be developed, agreed and tested before the details of the activities required can be outlined. Principles being used to develop this system include collective decision-making, consumer input and access by all VCCC partners. Steps to develop this system will include:

- agreement on criteria and processes for referral.
- agreement on processes for sample collection, transfer and storage.
- agreement on processes for reporting and evaluation.
- determining and testing the best way to provide collective decision-making around genomic testing and triaging samples for comprehensive cancer genomic panel assays or whole genome sequencing.

The VCCC Research & Education Leads in different tumour streams, in their leadership roles and with their established networks of expertise across the VCCC, will contribute to the collective decision-making required to ensure that the system to request genomic assays is based on best practice clinical judgements.

The investment in a Precision Oncology program will fund genomic testing by the Molecular Pathology Laboratory at Peter Mac and/or the University of Melbourne Centre for Cancer Research for a limited number of cancer patients for whom there is good evidence for an expectation of clinical benefit, but for whom testing is not yet reimbursed and a suitable research study is not available.

Milestones

Milestones have been outlined for the first 12 months of this program encompassing the setting up of a single integrated process for requesting genomic tests, genomic pathology, computational oncology and the Molecular Tumour Board. Once the key personnel are appointed and processes agreed and tested, milestones for 2019-2021 will be developed that will focus on assaying samples from patients. The integrated process will be evaluated on a six-monthly basis to enable continual improvements to be made.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Development of position descriptions for two curation scientists and a medical oncologist who will work across the Precision Oncology and New Approaches to Clinical Trials programs	Q4 2017
Appointment of two curation scientists and a medical oncologist	Q4 2017 - Q1 2018
Establishment of an expert and representative collective decision-making group whose function is to triage requests for genomic assays	Q1 2018

Agreement on how the expert and representative collective decision-making group will function including a system and guidelines for triaging requests for genomic assays	Q3 2018
Development of a system and guidelines for triaging requests for genomic assays	Q2 – Q3 2018
Training of curation scientists recruited to the program	Q1 – Q2 2018
First cases to be processed within the new system	Q3 – Q4 2018

Measures of Success

Measures of success that reflect the goals/ desired outcomes of the patient benefit from genomic testing are unlikely change significantly in the timeframe of the current funding agreement. Interim measures for which change will be seen in the medium and long term will therefore be process measures that demonstrate steps towards the goals/ desired outcomes including:

- numbers of referrals for genomic testing per VCCC partner organisation and per tumour stream.
- numbers of genomic tests.
- numbers of reports on genomic data communicated to the referring clinician or discussed at the. Molecular Tumour Board made in a clinically useful timeframe.
- adherence to developed guidelines on how best to apply different genomic pathology assays.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Curation scientists	Postdoctoral scientists 2 x1 FTE for 2 years	$400,000	Peter Mac and UoM
Medical oncologist to co-ordinate expert group, lead MTB, provide clinical expertise	0.2 FTE	$144,000	Partner
Program Manager, co-ordination and administrative support	0.2 FTE	$66,000	VCCC
On-costs			
All salaries	20%	$122,000	
Consultancies			
Direct Research Costs			
Genomic testing- comprehensive cancer genomic panels and whole genome sequencing	2 years	$700,000	
Enabling Facility Costs			
Other Costs			
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,477,000**	

Governance

The Precision Oncology program will have a Steering Group with appropriate scientific expertise, including expertise in the patient perspective, that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One scientific member and one clinical

member of the Steering Group will be a CRAC member. Staff employed within partner organisations will report to the appropriate member of the Steering Group. Working groups of appropriate representation and expertise will be convened when required to develop the system for referral for genomic testing. The system for requesting genomic tests will be overseen by a management group comprising the Steering Group with additional representative members and expert members- patient perspective.

Opportunities to enhance sustainability

- In the long term, molecular pathology is expected to be incorporated into standard care via MBS and other pathology funding.
- The Molecular Tumour Board has been sustained since 2013 with minimal funding and is likely to continue beyond this funding agreement due to the critical mass of interest that has been built. In the very long term, the functions of the Molecular Tumour Board will eventually become incorporated and subsumed into tumour stream multi-disciplinary meetings as genomic pathology expertise is expanded.

Program 3: Precision Prevention and Tailored Screening

The VCCC will invest around $800,000 in precision prevention and tailored screening.

The key elements of this program are:

- bringing together expertise in precision prevention and tailored screening, that is currently not well coordinated or connected, to identify opportunities to collaborate.
- developing consensus on a collaborative program of work that enhances research translation and impact.

Context

Precision prevention is defined as prevention that is tailored to individuals. Tailored screening considers an individual's risk profile when determining the approach to screening for cancer.

Prediction of people's future cancer risk (risk prediction) is a key component of both precision screening and prevention because it enables tailored screening programs and targeted prevention programs

Current risk prediction models are largely based on lifestyle risk factors and, to a lesser extent, genetic risk scores from genome wide association studies.

Rationale

A number of rationales for inclusion of a program in the fields of prevention and screening were identified:

- Prevention research is currently the smallest CSO (Common Scientific Ontology) field of cancer research across the VCCC in terms of research investment, activity and impact, yet has great potential to reduce the burden of cancer.
- The VCCC has clusters of expertise in precision prevention and tailored screening that are currently not well connected or coordinated.
- Over the past 20 years, research (supported by national and international grants) on personalised risk of some common cancers, such as breast and colorectal, has led to the development of risk models that can classify individuals into cancer risk strata. Therefore, in theory, prevention and screening strategies can be recommended based on personal risk. However, risk prediction models and new research and evidence on best practice for risk-stratified screening are not routinely translated into clinical practice or public health policy.
- Cancer screening programs that are targeted at high-risk individuals will have improved benefits and reduced harms, as well as increased cost-effectiveness.
- Supporting connectivity, plans and enablers in precision prevention and tailored screening translational research will enable researchers to be more competitive for major national and international grant funding.

Leverage and synergies

- Existing expertise in developing and validating better risk prediction models using genetic and behavioural risk factors.
- Links to cancer screening agencies such as BreastScreen Victoria.
- Cancer prevention activities at Cancer Council Victoria.

Connectivity with other priority programs

- Building Connectivity program: mechanisms to support connection of groups with complementary expertise.

- Research & Education Lead program: consensus on prevention and screening priorities for each tumour stream.
- Investigator-initiated Trial Capacity Building program: support for development of any agreed population-level clinical trials.

Goals/desired outcomes

Phase 1:

- An agreed program of work in the fields of precision prevention and tailored screening.

Overall program:

- Translation of suitable existing risk prediction methods or models closer to routine prevention and/or screening guidelines or practices.
- Across the VCCC, more research funding attracted to research into prevention and tailored screening, which currently have relatively low research activity.

Timelines

Because the best use of VCCC funding in the fields of precision prevention and tailored screening has not yet been identified, this program has been divided into two phases. During the first 12 month phase, a small amount of funding will be required to support the connection of groups with complementary expertise to identify opportunities for a collaborative program. A pool of funding has therefore been quarantined for the agreed program of work beginning in 2019.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Phase 1- connection and development	Q4 2017												
Phase 2- agreed program(s) of work	Q1 2019												

Activities

In the first phase of this program, the following activities will be undertaken to identify the best value investment for VCCC funding:

- support connection of groups with complementary expertise who want to develop risk stratified prevention studies and/or tailored screening trials to discuss relevant existing research and develop strategies and enablers for future prevention and screening studies.
- develop consensus on enablers to support precision prevention and tailored screening activities and/or translation of relevant research closer to routine practice.

Milestones

Milestones have been outlined for Phase 1 of this program. Milestones for Phase 2 will be developed during Phase 1 once the program of work for Phase 2 has been agreed.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Connection of groups with an interest or expertise in precision prevention and tailored screening	Q1 2018
A forum exploring relevant existing research and identifying opportunities and synergies for collective work in precision prevention and tailored screening.	Q2 2018
Consensus on identified prevention and screening priorities.	Q4 2018
Evaluation of program and priorities for movement into Phase 2.	Q4 2018

Beginning of Phase 2	Q1 2019

Measures of success

The key measure of success for Phase 1 of this program will be consensus across the VCCC partners on the focus and program of work for development in Phase 2. The Phase 2 program of work will be identified as that which can provide the greatest value-add for the VCCC partner organisations and the community more broadly. Measures of success for Phase 2 will be developed during Phase 1 once the program of work for Phase 2 has been agreed.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Program Manager, support for connection of relevant groups and development of consensus.	Phase 1 0.5 FTE 1.25 years	$68,750	VCCC
Program Manager, estimated for phase 2	Phase 2 0.2 FTE 1.75 years	$38,500	VCCC
On-costs			
Salaries	20%	$21,450	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Meetings and/or workshops		$30,000	
Funding for phase 2 which can support people, processes or enablers		$600,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$803,700**	

Governance

The Precision Prevention and Tailored Screening program will have a Steering Group with appropriate scientific expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. At least one member of the Steering Group will be a CRAC member. Working groups of appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

- Ongoing support for any enabled research in the fields of precision prevention and tailored screening is expected to be generated through new research grants.

Program 4: Understanding Response and Resistance to Targeted Therapies

The VCCC will invest around $940,000 in enablers that support research that seeks to understand the biological basis of both resistance and super-response to targeted therapies being explored in clinical trials at the VCCC.

The key elements of this program are creating and/or expanding collaborative networks that:

- create new capability and capacity in key platform technologies for biomarker assays.
- integrate Positron Emission Tomography (PET) molecular imaging data uniformly into assessment of response and resistance to targeted therapies in early Phase clinical trials.
- systematise and streamline targeted patient sample collection and distribution.

Context

Some patients are super-responders and others are resistant to the same targeted therapies, despite apparently having the same type of cancer, as characterised using current biomarkers.

Rationale

While targeted therapies are the future for improved outcomes for patients being treated for cancers with poor prognosis, patient selection remains the major barrier, especially in cancer types where only a minority of patients have durable responses to targeted therapies. This problem will be exacerbated as combinations of targeted therapies are increasingly being introduced. The need to match the right targeted therapies to each patient is recognised globally as a major challenge.

This program capitalises on strengths in VCCC partner organisations in:

- early phase trials of novel targeted therapies across tumour streams and across multiple hospitals.
- world leading expertise in PET imaging with novel tracers.
- research expertise in the biology relevant to some targeted therapies.
- cutting edge analytical platform technologies currently used for laboratory research.

The greatest value-adds to VCCC partner investments in early phase clinical trials, biological research relevant to targeted therapies and PET-based research from investment by the VCCC were identified as:

- creating and/or expanding collaborative structures/networks that enable internationally competitive research efforts into how to prospectively identify the right patient for specific targeted therapies.
- connecting and developing existing expertise to build a comprehensive suite of analytical platform technologies to address the biological basis of resistance and conversely super-response to targeted therapies that are in clinical trials at VCCC.
- greater use of PET imaging to assess response and/or resistance to targeted therapies in clinical trials.

With respect to PET imaging, this modality provides a different approach to monitoring biomarkers of response and resistance compared to more commonly utilised pathological approaches (eg biopsies and biomarker assays). Consequently, an aspect of this program will bring the world-leading expertise in *in vivo* imaging of metabolic and other biomarkers to research into response and resistance of targeted therapies. The program will therefore develop PET imaging as an important adjunct to the analytical technologies that are currently used to assess response and/or resistance to targeted therapies in clinical trials.

Leverage and synergies

- World leading expertise in PET imaging with novel tracers (Peter Mac and Austin Health) and emerging routine PET capability (SVHM and Western Health).
- Victorian Cancer Biobank and targeted sample collections among research groups.
- Successful models for co-ordinated open sample collections for research in some tumour streams.
- Work by the Melbourne Academic Centre for Health (MACH) to develop standard agreements for sample and data sharing.

Connectivity with other priority programs

- Precision Oncology program: existing and new DNA- and RNA-based genomics capabilities.
- Immunotherapy: co-ordination of existing relevant platform technologies.
- Building Connectivity program: mechanisms to support a collaborative network.

Goals/desired outcomes

- Enhanced expertise across the VCCC in targeted therapies, their clinical use and the latest techniques for predicting and assessing response to treatments.
- More patients accessing the right novel targeted therapies in clinical trials.
- More frequent use of PET imaging for assessing response in early Phase clinical trials, and better integration of PET imaging data, including from novel PET tracers, with genomic and biomarker data in multi-site clinical trials.
- Position the VCCC alliance as a global leader in international efforts to understand response and resistance to targeted therapies, capitalising on its competitiveness in early Phase clinical trials.

Timelines

Activities to support collaborative structures and networks to further translational research in response and resistance to targeted therapies and to build PET capability will commence in Q4 2017.

This program provides support for PET facilities at four VCCC hospitals to build the capability to be able to participate in clinical trials. It is expected that, once established, capability and expertise to enable greater use of PET imaging to assess response and/or resistance to targeted therapies in clinical trials will be self-supporting through funded trials within 2 years.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Capability and capacity in platform technologies	Q4 2017												
Streamline targeted patient sample collection	Q4 2017												
Build PET capability	Q4 2017												

Activities

Activities that will occur to better address the biological basis of response and resistance to targeted therapies include:

- supporting processes to enable samples from patients enrolled in clinical trials to be assayed for known, proof-of-concept or novel biomarkers of response and/or resistance to targeted therapies, including:
    - standard agreements for sample and data sharing.

- sample collection, transfer and storage.
- access to analytical platform technologies currently used for research.
- clinical data management and sharing.

- appointing a research assistant to prepare patient samples and conduct biomarker assays using key analytical platform technologies.
- conducting focussed annual scientific symposia that connect:
  - new science with clinical application in response and/or resistance to targeted therapies.
  - groups with different capabilities in analytical technologies with clinical expertise in targeted therapies.

Activities that will occur as part of building PET capability include:

- accredit PET facilities at SVHM and Western Health in order to be able to participate clinical trials
- build new capacity through appointment of new roles in physics, statistics and data management

Milestones

Milestones have been outlined for the first 12 months of this program. Once the key personnel are appointed and processes agreed, milestones for 2019- 2021 will be developed that will focus on assaying samples from and imaging of patients enrolled in clinical trials of targeted therapies.

Interim measures of success will be evaluated after 12 months, taking in to account the dependency of the success of this program on the number of targeted therapy clinical trials being conducted across VCCC partner hospitals.

A scientific symposium will be conducted within the first 12 months, and repeated yearly if evaluations are positive.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Development of position descriptions for new staff who will work across the VCCC	Q4 2017
Appointment of staff	Q4 2017- Q1 2018
Processes for sample collection, transfer and storage and standard arrangements for sample and data sharing developed and agreed	Q1-Q2 2018
Criteria for access to assays developed and agreed	Q1-Q2 2018
Engage consultant to accredit all 4 VCCC PET sites so they are “trial ready”	Q1 2018
First Annual Scientific Symposium	Q3 2018
Report on site PET accreditation	Q4 2018
Complete PET site accreditation	Q1 2019
Program evaluation	Q1 2019 then yearly

Measures of Success

Because this program is research-focussed, measures of success that reflect some of the goals/ desired outcomes are unlikely to be realised until the long term, i.e. beyond the timeframe of the current funding agreement. Interim measures will therefore be process measures that demonstrate steps towards the goals/ desired outcomes.

The measures of success for which changes will be seen in the medium to long term include:

- Number of different analytical technologies or platforms applied to clinical trial samples or clinical research projects that seek to understand the biological basis of response and resistance to targeted therapies.

- Number of collaborative projects between researchers working with specialist analytical technologies and clinicians researching response and resistance to targeted therapies.
- Number of PET instruments accredited to contribute to clinical trials.
- Number of patients undergoing PET imaging as part of a clinical trial of a targeted therapy.
- Number of clinical trial protocols developed that include biomarker assays for response and resistance to targeted therapies.
- Number of clinical trial protocols developed that include PET imaging for analysis of response and resistance to targeted therapies.
- Number of targeted therapy clinical trials utilising biomarker assays.
- Number of targeted therapy clinical trials utilising PET imaging.
- Number of targeted therapy clinical research projects utilising biomarker assays.

Some of the measures of success for which changes will be seen in the longer term are:

- Number of collaborative grants applied for.
- Number of collaborative grants received.
- Funding leveraged to support research that is part of the program.
- Number of collaborative publications.
- Impact of collaborative publications.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Project officer/ scientist to co-ordinate agreements for sample and data sharing, sample collection, transfer and storage, access to platform technologies and data management	1 FTE	$255,000	TBD
Research Assistant for sample preparation and platform assays (CyTOF in first instance)	0.5 FTE	$108,000	TBD
Technical officer- physics & statistics for PET development	0.25 FTE 2 years	$50,000	Austin Health
Data manager- PET data in clinical trials	1.5 FTE 2 years	$210,000	Austin Health, Peter Mac, SVHM & Western Health
Program manager- support for collaborative activities, meetings and symposia	0.2 EFT	$66,000	VCCC
On-costs			
Salaries		$138,000	
Consultancies			
Site accreditation for clinical trial grade PET	Year 1	$20,000	
Direct Research Costs			
Bench fees for research assistant	$5000 pa for 3 years	$15,000	
Enabling Facility Costs			
Other Costs			
Annual Scientific Symposia and other meetings		$30,000	

Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$937,000**	

Governance

The Understanding Response and Resistance to Targeted Therapies program will have a Steering Group with appropriate scientific expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the Steering Group will be a CRAC member.

Opportunities to enhance sustainability

- Development of PET imaging capability at all four VCCC sites is designed to be self-sustaining after year 2.
- Development of CyTOF technology will attract new research which will allow transition to user-pays funding in year 3.
- Streamlining of sample sourcing from clinical trials will create cost efficiencies for research projects, enabling embedding of sample acquisition into recurring research budgets.
- Ongoing support for clinical and translational research into response and resistance to targeted therapies is expected to be generated through new research grants.

Section B: Clinical Trials

Clinical trials drive improvements in cancer care. They also provide conduits for translation of discovery research into routine clinical practice.

The proposed VCCC clinical trial endeavour has been constructed to address current areas of greatest need and the most significant gaps in activity across the VCCC. The investment focusses on the areas where the VCCC has the potential to add the greatest value, while seeking to leverage the efforts of the many organisations already working towards improvements in clinical trials. In order to realise significant improvements in clinical trial participation, all the components of the system are to be addressed cohesively.

The proposed work has been organised into five broad areas, each comprising a number of programs.

These five areas are:

a) **Capacity building**
   - Program 5: Investigator-initiated Trial Capacity Building
   - Program 6: Building Capacity through Efficiency

b) **Expanding the trial portfolio**
   - Program 7: Building Trial Group Capability
   - Program 8: New Approaches to Clinical Trials
   - Program 9: Registry Trials

c) **Increasing access**
   - Program 10: Teletrials
   - Program 11: Increasing AYA clinical trial access
   - Program 12: Increasing awareness of clinical trials

d) **Developing the workforce**
   - Program 13: Development of workforce capacity and capability

e) **Measurement and impact**
   - Program 14: Metrics for clinical trial participation

Program 5: Investigator-initiated Trial Capacity Building

The VCCC will invest around $8m to provide the resources for more investigators to open and conduct a clinical trial.

The key elements of this program are the creation of:

- a VCCC Clinical Trial Development Hub to support idea generation, protocol development, mentoring of Investigators
- a VCCC Clinical Trial Assistance Scheme to provide access to resources to support the development, conduct and management of selected investigator-initiated and non-commercial trial

Context

Capacity for investigator-initiated trials is the single most frequently identified unmet need for the cancer clinical trials community.

Rationale

Demand for increased support for investigator-initiated trials was an almost universal request from stakeholders and seen as the highest strategic priority for the VCCC partnership from consultations between 2009 and 2016. This priority aligns with national work to identify unmet needs in the clinical trial sector that need addressing, including:

- the Australia-wide consultation conducted by the Australian Medical Research Advisory Board, which identified the facilitation of non-commercial clinical trials of potential significance as a key area of need that should be a focus for the Medical Research Future Fund (MRFF).
- the Australian Clinical Trial Alliance, has identified that while Australia has a strong track record in non-commercial, 'public-good' trials that have the capacity to lead to better health outcomes, the infrastructure to support such trials is not currently being addressed as part of efforts to improve the landscape for conducting clinical trials in Australia.

A number of other rationales for investment in investigator-initiated trials were identified including:

- investigator-initiated trials often ask questions that the pharmaceutical and biotech industries are unlikely to invest in, but that cancer patients benefit from.
- on average, non-commercial trials at VCCC sites recruit more patients per trial than commercially-sponsored trials.
- cost-effective access to support for study development and implementation, normally provided by clinical trial sponsors or contract research organisations (CROs), will remove barriers to start-up of VCCC investigator-initiated trials.
- provision of trial support functions, in a cost-effective and sustainable manner, will significantly increase the number of VCCC investigator-initiated trials.

Leverage and synergies

- The VCCC alliance has a critical mass of clinician researchers and so is ideally placed to contribute to 'public good' clinical research.
- Existing clinical trial services for investigators and co-operative groups within VCCC partners and academic clinical trial statistics capability.
- Existing clinical trial services for investigators and co-operative groups in other local and national groups.

Connectivity with other programs

- Development of Workforce Capacity and Capability program: mentoring for investigators.
- The Research and Education Lead program: mentoring of early-mid career investigators within each tumour stream, co-development of trial concepts by peers, facilitation of more collaborative, multi-site trials and better cross-referral of trial patients.
- Precision Prevention and Tailored Screening program: support to develop population-level tailored screening trials.

Goals/desired outcomes

- Increased number of high quality investigator-initiated clinical trials within the VCCC.
- Increased number of cancer patients enrolled in clinical trials.
- Increased and higher quality evidence for practice change.
- Greater numbers of experienced clinical trial investigators.
- High quality and consistent start up processes for investigator-initiated clinical trials.
- Consistent collection of data for non-commercial trials.

Timelines

This program provides support for a VCCC Clinical Trial Development Hub 2018 which will developed over 4-6 months from Q4 2017 and begin operating in pilot mode in Q1 2018. The hub will be fully operational in Q2 2018.

A VCCC Clinical Trial Assistance Scheme will be developed for 4-6 months from Q1 2018 and will begin operating in Q3 2018.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Clinical Trial Development Hub	Q4 2017 (development) Q1 2018 (operation)												
Clinical Trial Assistance Scheme	Q1 2018 (development) Q3 2018 (operation)												

Activities

A VCCC Clinical Trial Development Hub will be established. The hub will comprise an expert advisory council who will assist and mentor investigators in developing their novel trial concepts into protocol synopses, and who will evaluate proposals and select those that should move into a clinical trial assistance scheme.

Activities that will occur as part of the hub include:

- support for idea generation.
- support for protocol development.
- mentoring of investigators in:
    - developing the skills to develop and conduct investigator-initiated trials.
    - developing the relationships with industry to leverage commercial funding for investigator-initiated trials.
- access to biostatistics support prior to grant applications.
- assistance with grant applications so that grants submitted for funding of investigator-initiated and other non-commercial trials proposals are of high quality and more competitive for funding.
- selection of investigator-initiated trials to be supported through the VCCC Clinical Trial Assistance Scheme.

A VCCC Clinical Trial Assistance Scheme will be established. The scheme will provide the necessary infrastructure, through existing service providers, to support the development, conduct and management of selected investigator-initiated and non-commercial trials.

Activities that will occur as part of the scheme will include:

- Developing tenders and/or agreements with existing service providers to provide cost effective support for contract research organisation (CRO)-like functions, including protocol design, medical writing for protocols and other essential documents, development programmers to create case report forms, site monitoring, data collection and analysis and study reports.
- Developing tenders and/or agreements with existing service providers to provide cost effective support for trial management functions such as feasibilities, trial budget negotiations, contract agreements, ethics submissions, ethics amendments, governance submissions, accrual reporting, financial management and trial project management.

Milestones

Milestones have been outlined for the first 12 months of the program to coincide with the establishment of the hub and the scheme. Once the key personnel are appointed and processes have been agreed and tested, milestones for 2019-2020 will be developed that will focus on increasing the numbers of investigator-initiated trials. The program will be evaluated on a six-monthly basis to enable continual improvements to be made.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Establishment of Clinical Trial Development Hub	Q2 2018
Establish criteria and prioritisation framework for idea progression	Q2 2018
First submissions for support reviewed	Q2 2018
Launch of Clinical Trial Assistance Scheme	Q3 2018

Measures of Success

Measures of success for which change will be seen in the medium and long term will be those that focus on:

- the number of ideas developed into protocol synopses in the Clinical Trial Development Hub that are formally assessed for the Clinical Trial Assistance Scheme.
- the number of protocol synopses that are supported through the VCCC Clinical Trial Assistance Scheme.
- the number of investigator-initiated trials that attract grant, industry or philanthropic funding as a result of the support provided through the program.

Measures of success for which change will be seen in longer term will include:

- number of conference presentations from supported investigator initiated trials.
- number of publications arising from supported investigator initiated trials.
- number of guidelines using findings from supported investigator initiated trials.
- changes in practice regionally, nationally and internationally that align with trial results.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Project officer- co-ordinate submitted ideas and protocols and feedback to investigators	1 FTE	$210,000	VCCC
Program manager- contracting and co-ordinating external service providers to support development of trials	1 FTE	$330,000	VCCC
Project officer- assistance with and co-ordination of interactions between external service providers and investigators	1 FTE	$240,000	VCCC
On-costs			
Salaries		$156,000	
Consultancies			
External Service providers	50,000-$400,000 per trial	$6,800,000	
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Administration costs, licensing, consultants etc	Allow $100,00 pa for 3 years	$300,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$8,081,000**	

Governance

The Investigator-initiated Trial Capacity Building program will have a Steering Group with appropriate scientific expertise, including expertise in the patient perspective, that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. At least one member of the Steering Group will be a CRAC member.

The VCCC Clinical Trial Development Hub will draw on expertise from the VCCC Research & Education Leads and their networks and will include partner representative members, expert members and a patient perspective.

Opportunities to enhance sustainability

- Providing support to develop and open investigator initiated clinical trials will reduce trial costs required from grant funding, meaning that available grant funding can support more clinical trials.
- Potential to leverage NHMRC and MRFF funding for clinical trials.
- Ongoing "in kind" contribution of time by experienced clinician-researchers to the Clinical Trial Development Hub.

- Links to the Development of Workforce Capacity and Capability program to mentor and upskill investigators will ensure that new capability (skills and knowledge) for clinical trial investigators is embedded and sustained.

Program 6: Building Capacity through Efficiency

The VCCC will invest approximately $1.4m in building capacity in clinical trials.

The key element of this program is a series of complementary projects that aim to increase capacity by reducing administrative, governance and regulatory workload for trials across the VCCC.

Context

Clinical trials require substantial and costly infrastructure in order to be safe for patients, timely and cost-effective.

Rationale

- To increase both the number of cancer clinical trials and clinical trial participation, support for trial infrastructure growth is critical.
- Improving efficiency, quality and consistency of clinical trial management will decrease costs per trial and free up site staff time for clinical trial work by decreasing their administrative burden.
- Efficient processes are equally as important as patient care for high quality clinical trials.
- It is recognised that many bottlenecks in clinical trial processes are during start up, such as timelines for governance and ethics approvals.
- Streamlining the time taken to open clinical trials, including for governance and ethics approvals, will increase the attractiveness of VCCC sites to commercial trial sponsors.

Leverage and synergies

- Existing electronic ethics and governance systems.
- Cancer Trials Australia clinical trial services.

Connectivity with other programs

- Development of Workforce Capacity and Capability: training for new systems and processes.
- Teletrials: removing potential governance barriers.
- Increasing AYA Clinical Trial Access program: removing regulatory, administrative and/or governance barriers.

Goals/desired outcomes

- Increased efficiency, quality and consistency of opening and managing clinical trials at VCCC sites.
- Attraction of more commercially-sponsored trials.
- More clinical trials at VCCC sites.

Timelines

This program has been conceived as a series of complementary projects that aim to reduce the administrative, governance and regulatory workload for any VCCC trial. Because previous work to increase efficiency, for example the REx project to streamline multi-site ethics submission and approval, has demonstrated the importance of engagement of stakeholders in clinical trials units, research offices/directorates and other organisations, selected projects will not begin until Q4 2018.

Extensive engagement and planning will occur from Q4 2017 onwards to generate buy in from VCCC clinical trial sites.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Stakeholder work	Q4 2017												
Efficiency projects	Q4 2018												

Activities

During the first stakeholder engagement phase, activities will include:

- bringing together clinical trials managers to share experiences and to identify opportunities for greater efficiency through collaboration.
- identifying barriers to implementation of REx processes for streamlining and reducing timelines for multi-site ethical review.
- developing criteria for prioritising proposed efficiency and/or harmonisation projects, assessing how funding will be governed/reviewed for these projects.

Once potential efficiency and/or harmonisation projects are prioritised then agreed and planned, they will commence in a staged manner from late 2018 onwards.

Potential projects that have already been proposed during consultation with VCCC sites include:

- provision of independent quality assurance/quality control support services to assist sites to enhance trial quality and to ensure sites are audit ready.
- facilitating VCCC clinical trial radiotherapy quality assurance protocols to ensure sites involved in radiotherapy clinical trials are credentialed for advanced technology and techniques in radiation oncology trials such as Stereotactic Body Radiotherapy (SBRT) and Adaptive Radiotherapy.
- support or subsidisation of a uniform electronic filing system for VCCC sites to reduce the administrative workload and help sites be permanently audit ready.
- improving governance processes where beneficial and feasible.
- providing sites with access to standardised forms and templates (SOPs, budgets, contracts, amendments, finance, legal, project management) to reduce the administrative workload.

Milestones

Milestones have been outlined for the first 12 months of this program. Once prioritised projects have been agreed, milestones for 2019- 2021 will be developed for individual projects.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Establish position descriptions for program staff	Q4 2017
Appointment of staff	Q1 2018
Criteria and governance for prioritising and funding individual projects developed and agreed	Q2 2018
Agreement on area and methodology for first efficiency project	Q3 2018
Commencement of first efficiency project	Q4 2018

Measures of Success

Measures of success for the stakeholder phase of this program will be the number of prioritised efficiency and harmonisation projects generated and proceeded to implementation.

Once prioritised projects have been agreed, measures of success will be developed for each project.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Program manager	1 FTE	$330,000	VCCC
On-costs			
Salaries		$45,000	
Consultancies			
External Service providers- resources to implement projects	4-10 projects	$1,000,000	
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Meetings and events	3 years	$20,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,440,000**	

Governance

The Building Capacity through Efficiency program will have a Steering Group with appropriate expertise, that reports to CRAC. Review and governance of criteria and processes for prioritisation and funding of efficiency and harmonisation projects proposed and developed by the Steering Group will be provided by CRAC.

Opportunities to enhance sustainability

- Once efficiencies are embedded, resource requirements at sites will reduce significantly over the funding period, and need for recurrent funding will disappear.
- Ongoing "in kind" support from Clinical Trial Unit managers and Research Directorates at VCCC sites.

Program 7: Building Trial Group Capability

The VCCC will invest approximately $850,000 to enable clinicians from disciplines other than medical oncology and haematology to be investigators for cancer clinical trials.

The key elements of this program are:

- Development of academic leadership for disciplines aspiring to develop clinical trial activity
- Creating networks of clinicians and healthcare professionals across VCCC organisations
- Training and mentoring for new clinical trial investigators within the network
- Clinical Trial Fellowships
- Access to the new clinical trial capacity/resources and trained workforce

Context

The greatest barrier to increasing conduct of clinical research is protected research time for clinicians.

Rationale

VCCC partners already have large clinical trial portfolios in medical oncology and haematology. It was recognised that to expand numbers of clinical trials and patient participation in clinical trials, the portfolio of trials would need to be broadened to other disciplines by building new capability in these groups, as well as increasing capacity for medical oncology and haematology trials as part of the capacity building-focussed programs.

Creating new trial groups expands the patient pool with access to clinical trials as well as the expertise of the clinicians conducting the trials, and therefore the diversity of the types of clinical trials on offer, increasing the chances that a patient will be eligible for an open trial.

A number of other rationales for investment in building trial group capability were identified including:

- Medical oncologists and haematologists in large specialist hospitals generally have the expertise and experience to develop and run clinical trials. In contrast, clinicians from other cancer related disciplines have not had similar opportunities to develop the same skills.
- Most large clinical trials units are limited to medical oncology and haematology trials and the research staff are highly skilled, experienced and work with peers and mentors. Other disciplines have modest units and their research staff have significantly less experience and expertise.
- More clinical disciplines conducting trials generates more and better evidence for clinical practice in those disciplines.

A number of clinical disciplines were identified as potential groups to resource and support. Criteria for selection of which group to support first were developed and include:

- the number of patients who could potentially recruited to clinical trials in the discipline.
- the level of experience of clinicians in the discipline in clinical trials.
- patient demand for clinical trials in the field.
- the presence of academic leadership with research experience in the discipline.
- established networks of clinicians across hospitals in the discipline.
- opportunities to conduct sponsored (funded) trials as well as investigator initiated trials so that the trial group has the potential to develop a sustainable financial model for running clinical trials.

The rationale for Palliative Care as the first clinical discipline to be supported:

- There is a large pool of patients across the VCCC (up to 3000) who could potentially participate in palliative care clinical trials but currently do not have the opportunity to do so.

- Palliative care is one area that has long been highlighted by cancer patients and the community as a priority for generating new evidence and then timely translation into evidence-based clinical practice.
- Identification of an existing leader with the academic credentials and research experience to build a trials program, as well as the protected research time (in this case through an academic appointment) required to drive and lead a new trial group.
- There is an established palliative care network across the VCCC.
- There is opportunity to conduct sponsored (funded) palliative care trials along with investigator initiated trials, and this will assist significantly in establishing a sustainable financial model.

Leverage and synergies

- This program leverages some of the strategic academic appointments made under the Leaders in Cancer strategy including the newly appointed Chair of Palliative Medicine.

Connectivity with other programs

- Development of Workforce Capacity and Capability program for upskilling and mentoring investigators.
- Investigator-initiated Trial Capacity Building program and Building Capacity through Efficiency program for access to resources.

Goals/desired outcomes

- A greater diversity of clinical trials on offer at any one time at VCCC sites.
- More clinical trials in palliative care initially, then expanding to other disciplines such as supportive care, surgical oncology, allied health, radiation oncology and/or other groups when feasible.
- Establish clinical trials as standard practice within palliative care services.

Timelines

This program provides seed funding for a VCCC-wide palliative care trial group from the beginning of 2018 for a period of two years, after which time it is expected that that this group will be self-supporting. Based on readiness to proceed and available funds, subsequent trials groups will be identified and supported from year 3 onwards.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Palliative Care Clinical Trial Group	Q1 2018												
Subsequent Clinical Trial Groups	Q4 2019												

Activities

This program will build trial group capability by providing tailored leadership pathways for disciplines other than medical oncology and haematology. Investigators in other disciplines will then have the competencies and knowledge to be able to build a clinical trial portfolio in their field.

The pathway will include:

- Identifying and/or supporting clinician-researcher leaders who have the capacity, via protected research time, to drive new clinical trials enterprise in their clinical discipline. Mechanisms for

protecting research time will include facilitating the development of academic leadership for the field.

- Support for the clinician-researcher leadership role to build networks of clinicians and healthcare professionals across VCCC partners that form the foundation for collaborative multi-site clinical trials.
- Leveraging the professional development and mentoring capacity under the Development of Workforce Capacity and Capability program to provide training and mentoring that develops clinical trial investigators within the network. Mentoring would focus on:
    - developing the skills to develop and conduct investigator-initiated trials.
    - developing the relationships with industry and the business and strategic intelligence skills that help build a high quality and sustainable trial portfolio.
- Support to protect research time for clinical trial fellows, trial co-ordinators and an early-mid career clinician researcher (who will manage and co-ordinate the agreed clinical trials) for a limited period until the new trial group is self-sufficient.
- Access to the resources developed under the two clinical trial capacity building programs so as to reduce barriers to developing new trial portfolios.

The tailored pathway described above and its implementation will be evaluated over the course of the two-year period so that learnings can be applied to subsequent trials groups.

Milestones

Milestones have been outlined for the first 18 months of this program encompassing the setting up of a palliative care trial group. Once the key personnel are appointed and the initial palliative care clinical trials to be conducted have been agreed, milestones for 2019 will be developed that will focus on approvals of palliative care clinical trials and first patients enrolled. The palliative care element of the program will be evaluated yearly assist it becoming self-sustaining after year 2.

Milestones for building trial group capability for other specific individual trial groups will be developed over the first two years of the program.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Creation of a collaborative network of palliative care clinicians and healthcare professionals across VCCC organisations	Pre-existing
Creation of a scientific advisory group to support the Palliative Care collaborative group	Q4 2017
New clinical trial investigators within the palliative care collaborative access the program mentoring capabilities	Q3 2018
Development of and awarding of Clinical Trial Fellowships designed to work across multiple hospitals and appointment of a fellow	Q1 2018
Appointment of clinical trial personnel (coordinator(s) and/or research nurse(s)) across more than one VCCC site	Q1- Q2 2018
Palliative care clinical trial personnel (coordinator(s) and/or research nurse(s)) within the palliative care collaborative accessing training and/or professional development	Q2- Q3 2018
Agreement on initial clinical trials to developed	Q2 2018

Palliative care investigators having their concepts for trials prioritised for accessing to new clinical trial capacity/resources under the Investigator-initiated Trial Capacity Building and the the Building Capacity through Efficiency programs	Q2- Q4 2018
Development of a strategy to grow the palliative care clinical trial portfolio through a graded approach	Q2 2018- Q2 2019

Measures of Success

Changes in the measures of success that reflect the goals/desired outcomes of more palliative care clinical trials and more patients enrolled in palliative care clinical trials will be seen in the medium and long term, taking into account the time lags for new clinical trial programs.

Measures of success for which change will be seen in the medium to long term will include:

- Number of palliative care healthcare professionals at each site upskilled in essential clinical trials skills e.g. GCP training, data capture and analysis.
- Number of VCCC palliative care healthcare professionals involved in national and/or international co-operative research groups.
- Number of palliative care clinical trial protocols developed collaboratively.
- Number of palliative care clinical trials opened.
- Number of palliative care clinical trials available per VCCC site.
- Number of palliative care clinical trials open at more than one VCCC partner hospital.
- Number of categories of palliative care clinical trials based on primary endpoints e.g. target symptoms such as pain and nausea and number of trials open in each category.
- Number of eligible patients who are offered and have discussed clinical trial enrolment.
- Number of patients screened for palliative care clinical trials.
- Number of patients enrolled in studies.
- Perception of clinical trials by palliative care healthcare professionals.
- Development of pamphlets/information for patients and families around palliative care clinical trials.

Measures of success for building trial group capability for other disciplines, and therefore additional diversity in clinical trials, will be developed alongside development of new trials groups in those disciplines.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Clinical trial Fellows	1 FTE for year 1 1.4 FTE for year 2	$320,000	Multiple partners
Trial co-ordinators/ research nurses	1.2 FTE 2 years	$216,000	Multiple partners
Early-mid career clinician researcher	0.1 FTE 2 years	$59,000	Partner
Program Manager, co-ordination and administrative support	0.2 FTE	$66,000	VCCC
On-costs			
All salaries	20%	$132,200	
Consultancies			

Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Meetings and events	2 years	$10,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$848,200**	

Governance

The Palliative Care Clinical Trial Group and subsequent trial groups will each have a Steering Group with appropriate representation and expertise that reports to CRAC. One member of the Steering Group will be a CRAC member. Working and scientific advisory groups of appropriate partner representation and expertise will be convened when required to develop new palliative care clinical trials. Staff employed within partner organisations will report to the appropriate member of the Steering Group or a working/ advisory group. The high-level governance of the program, including selection of subsequent trials groups, will be overseen by CRAC.

Opportunities to enhance sustainability

- Trials groups will be assisted through mentoring in building a sustainable clinical trial portfolio. It is envisaged that trials groups will become self-sustaining over time as they attract recurrent commercial, philanthropic or competitive Government (NHMRC, MRFF) funding.
- Dissemination of learnings from assessment of the program will help the new capability become embedded.

Program 8: New Approaches to Clinical Trials

The VCCC will invest around $680,000 to build capability in the design and conduct of innovative trials involving molecular testing for predictive biomarkers.

The key element of this program is the set up and implementation of an N=1 trial.

Context

The design and conduct of cancer clinical trials is rapidly changing and the traditional, sequential three-Phase drug development paradigm is no longer always the most rapid way to bring some of the newer targeted therapies into routine clinical practice.

N=1 is a trial design in which a single patient is both the control and experimental arm of the trial through random allocation of the order in which an experimental and a control intervention are given. Response is measured at baseline, during treatment and after treatment to assess effectiveness of the experimental therapy in an individual patient. The N=1 trial design is therefore suited to precision oncology and targeted therapies

Rationale

Increased genomic testing of tumours means that patients can be better matched to a trial likely to benefit them. Currently, access to genomically-directed trials is largely through Phase I trials at VCCC partners. However, clinical trials of the right targeted therapy are not always available at the right time for the individual patient.

N=1 trials are a novel trial design that provides an option for patients with an actionable mutation to get access to a targeted therapy when a suitable clinical trial is not currently available for them. This program will therefore be a critical component of delivering on a Precision Oncology program for the VCCC and for Victorian patients.

N=1 studies also provide a framework to perform a preliminary evaluation of response to new therapies and to investigate predictors of response and mechanisms of resistance through biomarker evaluation.

Of the genomically-driven new approaches to trial design currently being used in the oncology setting, N=1 trials are currently the most applicable locally due to the design of the Precision Oncology program.

Leverage and synergies

- Existing genomic testing and reporting infrastructure including the Molecular Tumour Board.
- Research-grade capability in biomarker assays across the VCCC.
- Academic biostatisticians to support innovative clinical trial design.

Connectivity with other priority programs

- Precision Oncology program: these programs are highly linked as the N=1 trial provides an option to treat patients discussed at the Molecular Tumour Board for whom genomic pathology finds an actionable mutation but for whom a suitable clinical trial is not currently recruiting.
- Investigator-Initiated Trial Capacity Building: access to academic biostatistics and resources for trial initiation.

Goals/desired outcomes

More options for participation of patients, for whom molecular data about their tumour is known, in clinical trials of matched targeted therapies.

Timelines

This program will commence with the appointment of a medical oncologist in Q1 2018, who will set up the protocols and processes and gain the approvals required to implement an N=1 trial. It is envisaged that this study would be open for recruitment by the end of 2019.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
N=1 clinical trial	Q1 2018 (development) Q4 2019 (trial)												

Activities

- Establish a framework for N=1 trials.
- Develop and write a protocol for N=1 trials.
- Develop and agree new consent, ethics and governance processes required for efficient implementation of multi-site molecularly-directed trials.
- Develop agreements with pharmaceutical companies for access to targeted therapies.

Milestones

Milestones have been outlined for the first 2 years of this program encompassing the setting up of and approval of an N=1 trial. Milestones for 2019-2021 will be developed that will focus on recruitment of patients and reporting trial outcome data and biomarker analyses.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Establish position descriptions for a medical oncologist and a co-ordinator	Q1-Q2 2018
Appointment of staff	Q1 2018
Begin negotiation of access to targeted therapies	Q2 2018
Establishment of a framework and protocol for n=1 trials	Q3 2018
Ethics approval for first multi-site molecularly-directed N=1 trial	Q2 2019
First patient enrolled	Q4 2019

Measures of success

Measures of success will include:

- approval of trial protocol.
- number of agreements for access to targeted therapies.
- number of molecular targets covered by accessed therapies.
- number of patients discussed through the Molecular Tumour Board enrolled onto an N=1 trial.
- number of patients enrolled onto an N=1 trial.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Medical oncologist to develop protocol and negotiate agreements	0.6 FTE	$432,000	TBD
Project Officer, co-ordination of ethics and other submissions and administrative support	0.4 FTE	$96,000	VCCC and/or partner
On-costs			

All salaries	20%	$106,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$679,000**	

Governance

The program will have a Steering Group with appropriate scientific and clinical expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the Steering Group will be a CRAC member. Staff employed within partner organisations will report to the appropriate member of the Steering Group. Working groups of appropriate representation and expertise will be convened when required to develop the protocol and processes for the trial.

Opportunities to enhance sustainability

Once established, the N=1 approach to clinical trials will continue to leverage other programs focused on genomics and innovative clinical trials, and will be attractive to industry, philanthropic and competitive funding or support.

Program 9: Registry Trials

The VCCC will invest around $1.7m to develop a sustainable platform for registry-based randomised controlled trials.

The key elements of this program are:

- Conduct of a set of demonstration registry trials.
- Analysis and dissemination of the critical success factors for:
    - the registry trial methodology in the oncology setting.
    - the design of clinical registries that enable registry-based trials.

Context

Registry based trials combine the randomisation component from traditional clinical trials with real-world data from clinical registries. Internationally, these trials are increasingly being used to evaluate efficacy of commonly used treatments in large patient cohorts while controlling for confounding factors.

Rationale

Prospective registry-based randomised controlled trials (registry trials) is a new clinical trial design that offers the opportunity for large numbers of patients to participate in clinical trials through high recruitment rates of patients identified through existing clinical registries.

A number of other rationales for investment in registry trials were identified including:

- broadening the VCCC portfolio of clinical trials to new trial types creates the opportunity for more clinical trials, particularly investigator-initiated trials.
- registry trials provide the opportunity to answer pragmatic but important clinical questions.
- registry trials are a cost-effective trial methodology for randomised interventional trials with large numbers of enrolled patients.
- registry trials overcome some of the barriers to generalising results from traditional randomised clinical trials, involving restricted and relatively small patient numbers, by enrolling real-world patients seen in routine clinical practice.
- registry trials are a suitable methodology for trials of health service interventions that can inform, and be quickly translated into, routine clinical care.

The rationale for inclusion of an in-depth assessment of the critical success factors for the design and quality of clinical registries that enable registry-based trials is:

- registry trials are not yet commonly used in oncology, thus the efficacy, efficiency and quality of the registry-based trial approach needs to be demonstrated in the oncology setting to enable more wide-spread uptake.
- understanding and dissemination of these critical success factors to upskill investigators will be essential if sustainable capability in the conduct of this novel trial type is to be built.
- clinical registries are of variable quality and therefore often under-utilised and not cost effective to develop or maintain. This program therefore aims to define, disseminate and socialise the factors that make a clinical registry of the quality required for a registry trial, which will lift the quality of clinical registries as a side-benefit.
- the Australia-wide consultation conducted by the Australian Medical Research Advisory Board identified improving clinical registries as a key area of need that would be a focus for the MRFF.
- an academically rigorous assessment of the registry trial methodology in the oncology setting will have high local and international impact.

Leverage and synergies

- Existing, well-established clinical registries.
- Existing expertise in clinical registries at WEHI.
- Industry support for clinical registries collecting real-world data.
- Expertise in evaluation from the Centre for Health Policy at the School of Population and Global Health at the University of Melbourne.

Connectivity with other priority programs

- Building Analytical Capability for Data-driven Research program: linkage of clinical registries with complementary health data to enrich clinical registry datasets.
- Investigator-Initiated Trial Capacity Building: access to resources for investigator-initiated trials.
- Development of Workforce Capacity and Capability: upskilling investigators in registry trial methodology.

Goals/desired outcomes

- Establishment of registry-based trials as a trial methodology.
- High patient participation rates in registry trials for both common and uncommon cancers.
- Greater understanding of which trials and which questions are suitable for registry trials and more clinicians upskilled to conduct them.
- More clinical registries at a standard that permits them to be used for registry trials.

Timelines

This program provides support for up to six registry trials across a minimum of three tumour streams with the first trial opening in Q2 2018. Planning, protocol development and applications for ethics and governance approval for all trials will begin by Q4 2017 and subsequent trials will be opened for recruitment in a staged fashion from Q3 2018. It is expected that at least 4 approved trials will be open by Q1 2019. The postdoctoral researcher conducting the assessment will commence in Q1 2018.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
First registry trial	Q4 2017 (development) Q2 2018 (trial)												
Subsequent trials	Q1 2018 (development) Q3 2018- Q1 2019 (trials)												
Assessment	Q1 2018												

Activities

Demonstration trials in three different tumour streams using registries at different stages of maturity will be designed and conducted. Each trial will be assessed over the course of the trial so that critical success factors for both trial design and methodology and registry design and quality can be understood and documented. Each trial will be designed to answer pragmatic clinical questions in both common and rarer cancers. The aim is for two trials to be opened per tumour stream.

The tumour streams, sites and investigators will be selected according to agreed criteria, such as opportunity to proceed, anticipated patient recruitment, impact of the research on patients, and cancers with unmet needs by the Steering Group for the program with oversight by CRAC. The set of trials will be carefully selected to provide sufficient diversity so that learnings from the rigorous academic assessment will be maximised.

Activities to set up and open new registry trials for recruitment will include:

- Agreement on and confirmation of the validity of clinical questions for each registry trial.
- Upgrading clinical registries to be trial ready.
- Conducting feasibility assessments for each registry trial.
- Enlisting clinical trial sites to take part in each registry trial.
- Developing trial protocols for each registry trial.
- Writing and submitting application for ethical approval for each registry trial.
- Developing governance processes for each registry trial.

Protocol development for initial registry trials in agreed tumour streams will begin in Q4 2017.

Planning for the upgrade of the relevant existing clinical registries will being in Q4 2017. Planning for subsequent registry trials will begin in Q4 2017, then protocol development will begin in Q1 2018 and these trials will be successively approved and opened by Q3 2018.

The academic assessment and evaluation of registry trials will include:

- review of registry database design.
- inventory of existing registries, and analysis of their content, quality and upgrades needed to be trial ready.
- comparison of registry trial feasibility for common versus rarer cancers.
- applying for ethical approval for qualitative research.
- qualitative research (interviews and surveys) to determine the barriers and enablers to clinician involvement in and patient recruitment to registry trials.
- feedback of learnings into refinements of registry trial protocol design.

Dissemination activities will include:

- publication in peer reviewed journals.
- forums and workshops to inform investigators how to conduct registry trials and what are the critical success factors for the conduct of registry trials.
- discussion of registry trials at multi-disciplinary meetings and other routine clinical settings.

Milestones

Milestones have been outlined until the end of the funding agreement in Q3 2020. It is expected that recruitment into the trials will extend beyond Q3 2020. Results from the assessment will be reported at intervals that allow refinement and improvement of the registry trial design and protocols.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Establish position descriptions for program staff	Q4 2017
Appointment of staff	Q4 2017-2 2018
Agreement on criteria for selecting demonstration trials	Q4 2017
Selection of the first registry trial according to the agreed criteria	Q4 2017
Commence assessment work	Q1 2018
Begin upgrade of registry for tumour stream 1	Q4 2017
Finalise protocols for first registry trial for tumour stream 1	Q4 2017
Ethics and governance approvals for first registry trial for tumour stream 1	Q1 2018
Open first registry trial for tumour stream 1and first patient recruited	Q2 2018

Selection of a further 3 demonstration registry trials in 3 different tumour streams according to the agreed criteria	Q1 2018
Begin upgrade of subsequent 2 clinical registries	Q1 2018
Conduct planning and feasibility for agreed 3 registry trials	Q1 2018
Finalise protocols for agreed 3 registry trials	Q2 2018
Ethics and governance approvals for agreed 3 registry trials	Q2 2018
Open trial and first patient recruited for agreed 3 registry trials	Q3 2018
Conduct planning and feasibility a further 2 registry trials in 2 tumour streams	Q2 2018
Finalise protocols for next 2 agreed registry trials	Q3 2018
Ethics and governance approvals for 2 agreed registry trials pending feasibility of trial designs	Q3 2018
Open trial and first patient recruited for 2 agreed registry trials if approved	Q4 2018- Q1 2019
Annual meeting of VCCC clinicians involved in registry trials	Q3 2019
Present assessment results and refine registry trial methodology	Q4 2019
Meeting of clinicians in each tumour stream to present individual trial data	Q2 2020
Annual meeting of VCCC clinicians involved in registry trials	Q3 2020
Trial assessment findings to be disseminated broadly through a forum	Q3 2020

Measures of Success

Measures of success will be related to both the conduct of registry trials and increased knowledge about the conduct of registry trials and will include:

- Successful evaluation of initial registry trials.
- Number of patients recruited in registry trials.
- Proportion of eligible patients enrolled.
- Proportion of patients that are in the clinical registry who discuss a registry trial for which they are eligible in the clinic.
- Number of investigators who have attended a workshop on registry trials.
- Number of new trial protocols developed using existing registries.
- Number of new registries developed.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Clinical trial Fellows - 1 for each of 3 tumour streams	0.4-0.6 FTE x 3	$486,000	Multiple partners
Trial co-ordinators/ project officers- co-ordination, administration, governance	1.8 FTE	$388,800	Multiple partners
Research fellow level B- assessment and evaluation of critical success factors for trials and registries	1 FTE	$307,500	Partner
Program Manager, co-ordination and administrative support	0.2 FTE	$66,000	VCCC
On-costs			
All salaries	20-30%	$319,950	

Consultancies			
Direct Research Costs			
Redevelopment of databases and establishment of registry trial database		$100,000	
Interview transcription- assessment element		$4000	
Enabling Facility Costs			
Other Costs			
Meetings and events		$10,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,727,250**	

Governance

The Registry trials program will have a Steering Group with appropriate expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the Steering Group will be a CRAC member. CRAC will provide high level oversight, especially for the development and assessment of agreed criteria for trial selection.

Opportunities to enhance sustainability

- The program is designed to build new capability for clinical trial investigators in a novel trial design. The first three demonstration trials are designed to be worked examples that will allow critical success factors to be defined and disseminated, and processes to be refined, so that more investigators can use this trial design to give more patients opportunities to participate in clinical trials.
- Dissemination of expertise in registry trials will enable this trial design to become embedded in the portfolio of VCCC clinical trials.
- Successfully conducted and reported registry-based trials will increase the chance of success of funding applications for subsequent registry trials.
- Well-designed and curated clinical registries will support many research projects apart from registry trials, and therefore attract research funding to sustain them.

Program 10: Teletrials

The VCCC will invest around $1.5m in a teletrials program to provide rural and regional Victorians with the opportunity to have more of their cancer clinical trial-related treatment closer to home.

The key elements of this program are:

- Building partnerships and networks with regional cancer services through appointment of Regional Oncology Leads by the VCCC who will champion the program.
- Implementation and evaluation of pilot teletrials.

Context

Tele-oncology models of care have been demonstrated to improve the delivery of specialist health care to rural and regional patients, including the administration of sometimes complex chemotherapy.

Rationale

It is well accepted that proportionally fewer patients from rural/regional Victoria, compared to metropolitan Melbourne, participate in cancer clinical trials. The key barrier to equitable access to clinical trials for rural and regional cancer patients is the increased cost and time required by patients to travel to Melbourne to participate in clinical trials.

A number of other rationales for investment in a teletrials program were identified including:

- inequitable access to clinical trials is a factor in poorer cancer outcomes for regional and rural Victorians.
- teletrials enable rural and regional patients to have as much as possible of their trial-related treatment closer to home and therefore have the potential to reduce the burden of trial participation for patients without compromising safety.
- teletrials complement regional clinical trial networks by providing patients with access to clinical trials that are not open at regional hospitals.

Leverage and synergies

- The existing COSA Australasian Tele-Trial Model.
- Existing tele-oncology models of care established at Peter Mac, SVHM and RCH and telehealth models for other disease areas at VCCC hospitals.
- Established relationships between VCCC hospitals and regional centres.
- The recently established Victorian Regional Cancer Clinical Trial Network.

Connectivity with other priority programs

- Building Capacity through Efficiency program: for new governance processes.
- Development of Workforce Capacity and Capability program: upskilling regional and VCCC healthcare professionals to support a telehealth-based shared care model for clinical trials.

Goals/desired outcomes

- Improved access to cancer clinical trials for patients living in regional and rural Victoria.
- Increased participation in cancer clinical trials for patients living in regional and rural Victoria.
- Reduced burden of participation in cancer clinical trials, including time, cost and social disruption, for patients living in regional and rural Victoria.

Timelines

Planning for the first tranche of pilot teletrials will commence in Q4 2017. The first 3 teletrials are expected to open for recruitment by Q4 2018. An initial process evaluation will be conducted within 3–6 months after recruitment of the first patient. A full evaluation will be conducted approximately 18 months after recruitment of the first patient. It is expected that the first tranche of trials will have finished recruiting within 1–2 years after opening, and therefore evaluation of the impact of the teletrials on participation of rural/regional cancer patients will be feasible at that time. A second tranche of pilots will be set up after the process evaluation of the first tranche of pilots is complete, in order to incorporate refinements based on the learnings from the first tranche into the design of the second tranche.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
First 3 pilot teletrials	Q4 2017 (development) Q4 2018 (trials)												
Second tranche of pilot teletrials	Q1 2019 (development) Q4 2019 (trials)												

Activities

The Regional Oncology Leads were appointed in September 2017.

Activities that will occur as part of setting up the pilot teletrials include:

- developing criteria regarding the type of clinical trials that can be implemented as a teletrial.
- working with the Regional Oncology Leads and VCCC clinical trial sites to identify potential clinical trial sites at which to pilot a teletrial, including which site will be the primary site and which site will be the satellite. The 3 pilot teletrials will each have one primary and one satellite site.
- working with VCCC health services that have established telehealth models of care to identify barriers and enablers to the use of telehealth in oncology and conduct work to reduce any logistical barriers to a telehealth-based shared care model for clinical trials at the chosen sites.
- once a pilot teletrial and sites have been chosen, reviewing the feasibility of the trial regarding:
    - ethical, regulatory and sponsor feasibility and acceptability.
    - the capacity and capability of the satellite sites e.g. hospital pharmacy to support the teletrial.
    - stakeholder acceptability.
- conducting any required training for staff at the satellite site.
- developing and agree supervision plans, required agreements and all processes e.g. consenting patients, medication handling.
- developing and agreeing standard operating procedures for teletrials that conform to the COSA model.
- writing and submitting ethics, governance and Site Specific Approval documents.

After the first tranche of pilot teletrials have been opened for recruitment, a process evaluation will be conducted that is designed to inform the design of the second tranche of pilot teletrials. These trials are expected to test a more complex cluster model (a single primary site and multiple satellite sites).

Activities involved in the final evaluation of the pilot teletrials will include:

- evaluating whether the pilot teletrials were effective at increasing participation of rural/regional patients in cancer clinical trials.
- evaluating the cost of establishing a teletrial against the increase in the number of participants and the reported reduction in the burden of trial participation for regional and rural patients.

- developing a plan for ongoing training in the conduct of teletrials, informed by a needs analysis of training of both rural/regional and metropolitan healthcare professionals and the learnings from the pilot teletrial.

Milestones

Milestones have been outlined for two tranches of pilot teletrials using two different models (single primary site and single or multiple satellite sites).

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Agreement on the first tranche of pilot trials and the primary and satellite sites for each	Q1 2018
Contracts finalised between primary and satellite sites	Q2 2018
Key staff identified and trained	Q2 2018
Clinical trial sponsors contracted and protocols finalised	Q2 2018
Complete needs analysis for training in teletrials	Q4 2018
Ethics and governance approvals	Q3 2018
Trial opened and first patient recruited	Q4 2018
Process evaluation report	Q1 2019
Final evaluation report	Q3 2020
Agreement on second tranche of pilot trials and the primary and satellite sites for each	Q1 2019
Contracts finalised between primary and satellite sites	Q2 2019
Key staff identified and trained	Q2 2019
Clinical trial sponsors contracted and protocols finalised	Q3 2019
Ethics and governance approvals	Q3 2019
Required staff training complete	Q3 2019
Trial opened and first patient recruited	Q4 2019
Process evaluation report	Q3 2020

Measures of Success

Measures of success will be related to both the conduct of teletrials and increased knowledge about the conduct of teletrials and will include:

- Number of rural/regional patients recruited to a teletrial.
- Number of eligible rural/regional patients participating in a metropolitan-based clinical trial via tele-health.
- Number of patients seen at a rural/regional hospital who have a teletrial for which they are eligible discussed with them in the clinic.
- Number of investigators who report knowledge and experience of conducting teletrial.
- Number of healthcare professionals who have attended a training session on teletrials.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Regional Oncology Leads	0.2 FTE x 1.5 years x 1 0.1 FTE x 1.5 years x 1	$180,000	External health service
Support staff- 0.2 FTE per satellite site	0.2 FTE x 1.5 years x 3	$72,000	External health service

Education Development Manager- includes needs analysis	0.4 FTE 1 years	$40,000	VCCC
Program Manager, co-ordination, logistical and administrative support	1 FTE 1.5 years	$165,000	VCCC
On-costs			
All salaries	20%	$55,400	
Consultancies			
Health economics assessment		$10,000	
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Trial costs eg ethics submission, project management	For 3 trials	$90,000	
Travel	1.5 years	$35,000	
Education and training costs	1.5 years	$30,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$722,400**	

If the first pilots are successful, the VCCC Teletrials program will test a second model (cluster model with multiple satellite sites).

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Regional Oncology Leads	0.2 FTE x 1.5 years x 1 0.1 FTE x 1.5 years x 1	$180,000	External health service
Support staff- 0.2 FTE per satellite site	0.2 FTE 1.5 years x 7	$160,000	External health service
Education Development Manager	0.2 FTE 1 years	$20,000	VCCC
Program Manager, co-ordination, logistical and administrative support	1 FTE 1.5 years	$165,000	VCCC
On-costs			
All salaries	20%	$69,000	
Consultancies			
Health economics assessment		$10,000	
Direct Research Costs			
Other Costs			
Travel	1.5 years	$35,000	
Education and training costs	1.5 years	$10,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$694,500**	

Governance

The Teletrials program will have a Steering Group with appropriate expertise that reports to CRAC. The education and training element of the program will be overseen by CETAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. At least one member of the Steering Group will be a CRAC member. Both Regional Oncology Leads will be members of the Steering Group. Working Groups with appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

- Dissemination of new expertise in teletrials will increase the knowledge and uptake of this trial design and eventually embed teletrials within the Victorian clinical trial system.
- Costs of teletrials will eventually be incorporated into budgets of future commercial trials.

Program 11: Increasing AYA Clinical Trial Access

The VCCC will invest around $340,000 to facilitate the participation of adolescent and young adult (AYA) cancer patients in clinical trials, irrespective of whether that trial is open at an adult or paediatric hospital.

The key element of this program is implementing new administrative and governance processes that remove identified barriers to AYA clinical trial access.

Rationale

- AYA patients are enrolled into cancer clinical trials at a lower rate than for adults or for younger children, which may contribute to poorer outcomes for this group of patients.
- Novel targeted therapy trials often cater only for adults or for children, consequently 18–25 year olds are unable to access clinical trials primarily designed for paediatric patients that are open at RCH, while 15–17 year old cancer patients at RCH are unable to access clinical trials at adult hospitals.
- Many AYA cancer patients have rare cancers and trials for these cancers are typically not open at multiple sites.
- Administrative barriers have been identified as one factor that can prevent adolescent and young adult (AYA) cancer patients from accessing clinical trials from which they would gain significant benefit.

Leverage and synergies

- Paediatric care facilities, clinical trials experience and support services at RCH.
- Existing relationships between paediatric oncologists and adult oncologists across the VCCC partner hospitals.
- Preliminary work to streamline governance for clinical research across UoM-associated hospitals.

Connectivity with other priority programs

- Building Capacity through Efficiency program: improving governance processes at all VCCC sites.

Goals/desired outcomes

- Removal of barriers for adolescent and young adult (AYA) cancer patients to access clinical trials for which they should be eligible.
- A greater number of AYA cancer patients participating in clinical trials which may provide them with a significant benefit.

Timelines

This program provides support for work to agree, create and evaluate new processes. Work will begin in mid-2018 and be completed within 2 years.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Increasing AYA clinical trial access	Q3 2018												

Activities

Work to agree, create and evaluate new processes will include the following activities:

- conducting stakeholder meetings to identify barriers and agree on the work program.
- mapping current processes and identifying changes that can be made.

- identifying and socialising champions at each VCCC site, expertise in the processes required at each site and potential communication channels between sites.
- establishing new administrative, governance or other processes that support participation of AYA patients in a clinical trial while potentially having other parts of their treatment conducted at different sites.
- writing and socialising guidelines and or Standard Operating Procedures for referral of AYA patients to different sites.
- validating that proposed new processes meet all regulatory requirements.

Milestones

Milestones have been outlined for the first 12 months of this program. Once the key personnel are appointed and processes agreed, milestones for year 2 will be developed that will be specific for the agreed process changes and will focus on implementation.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q1 2018
Establish a working group comprising key stakeholders from within the VCCC alliance	Q2 2018
Report on mapping of processes and barriers	Q2-Q3 2018
Proposed guidelines and or Standard Operating Procedures for referral of AYA patients to different sites complete	Q4 2018

Measures of Success

Measures of success will include:

- number of AYA patients who have a clinical trial for which they are potentially eligible discussed with them in the clinic.
- number of AYA patients referred between VCCC hospitals to assess enrolment in a trial.
- number of AYA patients recruited to a paediatric or an adult cancer clinical trial.
- number of investigators who report knowledge and/or understanding of new processes.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Project Manager- experience in regulatory/ ethics/governance processes	1 FTE 2 years	$220,000	Partner
On-costs			
All salaries	20%	$44,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Education and training costs	2 years	$30,000	

Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$339,000**	

Governance

The Increasing AYA Clinical Trial Access program will have a Steering Group with appropriate expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. At least one member of the Steering Group will be a CRAC member. The project manager will report to the Steering Group. At least one member of the Steering Group will be a paediatric oncologist. Working Groups with appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

Established processes will be enduring, and it is anticipated that recurrent funding will not be required.

Program 12: Increasing Awareness of Clinical Trials

The VCCC will invest up to $860,000 in increasing awareness of clinical trials and therefore opportunities for patient participation.

The key elements of this program aim to support awareness of actively recruiting cancer clinical trials through:

- a feasibility study of real time updates to the Victorian Cancer Trials Link (VCTL) clinical trial website and app.
- a co-ordination resource to supplement the VCTL clinical trial app and website to streamline awareness of actively recruiting Phase 1 trials.

Context

The VCTL app provides a search interface to find recruiting trials. Searchable fields include tumour type, trial location and keywords as well as advanced search options including inclusion criteria such as age and molecular target, as well as trial Phase.

The VCTL website (http://trials.cancervic.org.au/) uses the same data as in the VCTL app but provides information in a user-friendly format and in plain English. The data is searchable by cancer type and advanced search options including trial location are available. The website includes factsheets, questions for patients to ask their doctor, patient stories, frequently asked questions, common myths about trials, links to other clinical trial information and resources and a link to Trial Connect.

Rationale

Patient awareness of clinical trials falls into 2 broad areas:

- general awareness of clinical trials as an option for part of their treatment or for accessing drugs that may not otherwise be available or may incur significant cost.
- awareness of specific cancer clinical trials that are recruiting at that point in time.

It is well recognised that multiple factors influence patients' decisions to participate in clinical trials of which awareness is only one factor. It is also well recognised that patients and carers are not uniform in the depth of information they want about clinical trials or their preferred way of receiving the information. A significant proportion prefer to receive this information from their treating clinician, which is why clinician awareness of clinical trials that are recruiting at the time is an important aspect to patient awareness.

The most frequently reported barrier to improving clinician awareness of clinical trials through use of the VCTL website and app is that information is updated manually and therefore often out of date - particularly information on when a trial is open for recruitment. Real time information, with automated updates to the VCTL website and app, have the potential to be a cost-effective way to increase the use of these resources by clinicians and therefore awareness of currently recruiting clinical trials.

Awareness of currently open Phase 1 trials presents a distinct challenge, as the status of Phase 1 trials changes particularly rapidly and so requires a hands-on approach to ensure seamless patient referral to major Phase 1 sites. Currently, Victoria has three clinical trial units with established and internationally recognised early drug development programs (the Parkville Cancer Clinical Trials Unit, Austin Health, and Monash Medical Centre).

Patient referral pathways to Phase 1 trial sites are currently ad-hoc, largely because there is no dedicated resource available to help manage referrals and track patient flow in relation to eventual access to potential trials. Evaluation of a pilot model for co-ordination of referrals to the Phase 1 trial unit previously

at the Royal Melbourne Hospital demonstrated that 24% of referred patients were accrued onto Phase 1 trials. This pilot demonstrated that funding for a co-ordinator, who has responsibility for referrals and eventual trial enrolment, was a cost-effective means of ensuring that clinicians were aware of which Phase 1 trials were open at which sites. The pilot also showed that patients were referred to the site where trials for which they may be eligible were open.

Leverage and synergies

- The well-established VCTL website and app, including the recently upgraded website designed to increase usability for cancer patients.
- High quality information about clinical trials for patients and families produced by Cancer Council Victoria.
- The existing Phase 1 Group facilitated by CTA that provides a network and forum for investigators to discuss open Phase I studies.
- Existing strong record of collaboration and productive working relationships across Phase 1 trial sites.
- Existing strengths in Phase 1 trials including harmonised processes for establishing and managing trials and existing mechanisms for engaging with Pharma and Biotech in an organised and structured manner.

Connectivity with other priority programs

- Precision Oncology program: access to molecular testing infrastructure.
- New Approaches to Clinical Trials program: N=1 trial.

Goals/desired outcomes

- Continued improvements to and greater usage of the VCTL website and app
- Improved participation in clinical trials
- Better co-ordination of referrals for all Victorian patients:
    - to all Victorian Phase 1 trial centres
    - to molecular/genomic biomarker-based pre-screening for Phase 1 trials

and therefore better recruitment to Phase 1 trials.

Timelines

The element of this program that enables co-ordination of patient referrals between three Phase 1 sites will commence in Q2 2018 with appointments expected in Q3 2018. Scoping for the feasibility study will begin in Q4 2017 and the study itself will begin in Q4 2018.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Feasibility study of real time VCTL	Q4 2017 (set up) Q4 2018 (feasibility study)												
Co-ordination of Phase 1 referrals	Q2 2018 (set up)												

Activities

To conduct a feasibility study of real time updates to the VCTL clinical trial website and app, activities will include:

- establishing a partnership with the team from Cancer Council Victoria who have developed the clinical trial app and the VCTL website.

- testing the feasibility of automated, real time updating of VCTL clinical trial status data (real time information on when trials are opened, recruiting or closed to recruitment) from at least 2 VCCC sites.
- planning for the next Phase of this work together with CCV depending on the outcomes of the feasibility study.

To improve co-ordination of patient referrals between three Phase 1 sites, activities will include:

- employment of co-ordinators to facilitate seamless patient referral to Phase 1 sites and co-ordination of molecular testing for trials with rare molecular subtypes.
- other roles for coordinators will enhance collective initiatives such as:
    - communication about trials and trial cohorts at each site via weekly updates.
    - development and upkeep of a database to enable patient tracking at each Phase 1 site.
    - liaising with CCV regarding data for the VCTL.

Milestones

Milestones have been outlined for the co-ordinators facilitating patient referrals to Phase 1 sites until Q2 2018. Once the key personnel are appointed and processes agreed, milestones for Q3 2018-2020 will be developed that will focus on streamlined referral to Phase 1 trials. Milestones for the feasibility study of real time updates to the VCTL clinical trial website and app will be developed during first stage of stakeholder engagement and mapping of processes.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Engagement of stakeholders	Q4 2017
Complete process mapping	Q2 2018
Determination of requirements for real time updates of information on when a trial is open for recruitment	Q2 2018
Procurement / contract for ICT consultancy	TBC
Implementation of solution	TBC
Develop position description for Phase 1 Co-Ordinators	Q1 2018
Appointment of staff	Q2 2018

Measures of success

The measures of success for the feasibility study of real time updates to the Victorian Cancer Trials Link (VCTL) clinical trial website and app will be determination of whether data can be pulled from VCCC partner sites into the VCTL database in real time.

The measures of success for the co-ordination resource (to streamline awareness of actively recruiting Phase 1 trials) for which change will be seen in the medium to long term include:

- Number of patients referred (cross-referrals, referrals from metropolitan and regional centres, and referrals from the private vs public sector).
- Number of patients referred for molecular testing for molecularly-directed trials that are only open at 1 site.
- Number of clinical staff aware of Phase 1 trials open at their own hospital.
- Number of clinical staff aware of Phase 1 trials open at the other Phase 1 sites.

Measures assessable in the longer term include:

- Number of eligible patients who are offered and have discussed clinical trial enrolment.
- Number of patients being pre-screened for Phase 1 studies.

- Number of patients enrolled in Phase 1 trials.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Program manager	0.2 FTE	$66,000	VCCC
Clinical Trial Co-ordinators at 3 Phase 1 sites	2 FTE for 2.5 years	$450,000	Multiple sites
On-costs			
Salaries		$103,200	
Consultancies			
IT consultancy for exploring real time updates		$200,000	
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$864,200**	

Governance

The Increasing Awareness of Clinical Trials program will have a Steering Group with appropriate scientific expertise that reports to CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the Steering Group will be a CRAC member. Working groups of appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

- Real time automated updates of the VCTL website and app will reduce manual collection and updating of data and therefore associated costs.
- Systems to update information in real time will be enduring once established.
- Demonstrating improvements in patient referrals and patient accrual to these Phase I sites will provide a justification for ongoing investment from each site's clinical trials program.

Program 13: Development of Workforce Capacity and Capability

The VCCC will invest $1.8m in a cancer clinical trials education/professional development program that contributes to the development of a highly trained clinical trial workforce that can meet the demand for greater clinical trial activity across the VCCC, state-wide and nationally.

The key elements of this program are:

- A granular needs analysis.
- Competency frameworks for key sections of the clinical trial workforce.
- Development of new education and training offerings to meet unmet needs at upskills the workforce to have the required competencies.

Rationale

This program addresses a recognised deficit in a highly trained clinical trial workforce to meet the demand for greater clinical trial activity and access to a breadth of trials across the VCCC and state-wide.

A number of other rationales for investment in a Development of Workforce Capacity and Capability program for clinical trials were identified including:

- Development of the clinical trials workforce has been consistently identified as a priority over many years.
- Expansion of clinical trial activity so more patients can participate is the major focus of the VCCC clinical trial program, but the clinical trial workforce is currently rate-limiting.
- There are currently no professional development pathways supported by a recognised, best-practice education program for the clinical trial workforce.
- Nurses form the largest component of the health workforce in metropolitan, regional and rural areas, thus they will be an initial target for clinical trial workforce development.
- PhD and post-doctoral laboratory research scientists are a potential skilled workforce who could enter the clinical trials research profession if they had the appropriate skills and experience.

Leverage and Synergies

- Existing training and workshops at VCCC partners and private providers including GCP training and the Graduate Certificate of Clinical Research (UoM).
- The existing Learning Management System (UoM).
- A successful pilot conducted by the Parkville Cancer Clinical Trials Unit to train PhD students as study coordinators through part time work experience and on-the-job training.

Connectivity with Other Priority Programs

This program underpins all the clinical trial related programs:

- Masters of Cancer Sciences: an education and training program that contributes to building the future cancer workforce for Victoria and contains two Cancer Research subjects.
- Building Nursing Research Capability program: aims to upskill nurses to develop and lead clinical trial research focused on improving patient experience, patient outcomes and efficiency of health services.
- Building Connectivity program: facilitation of specific workforce groups getting together.
- Research and Education Lead program: provides a mechanism for knowledge translation that facilitates practice change across the VCCC partnership.

Goals/desired outcomes

Develop workforce competencies and capability to:

- increase numbers of and upskill research nurses supporting and coordinating clinical trials.
- increase numbers of and upskill cancer clinicians to have the skills and experience to be investigators on clinical trials and to attract industry-sponsored clinical trials.
- upskill key cancer clinicians and trial managers in advanced skills such as the business management and business development aspects of the clinical trial system.
- increase numbers of scientists, including PhD-trained scientists, who have the skills to be study coordinators.

Timelines

Because the specific needs of the clinical trial workforce have not yet been identified at a granular level, and mapping of the current workforce and available education and training offerings has not yet been conducted systematically, the first phase of this program will focus on a needs analysis. Phase 2 will focus on development of a competency framework for research nurses. Phase 3 will focus on developing and delivering the training identified as unmet needs in phase 1 to enable the workforce to gain the required competencies identified in phase 2.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Scoping/needs analysis	Q4 2017												
Competency framework development	Q2 2018												
Program development and delivery	Q3 2018												

Activities

During phase 1, a granular needs analysis will be conducted that will include:

- mapping of and definition of (eg. disciplines /craft groups) the clinical trials workforce across the VCCC and regional Victoria, including current competencies for each role.
- a needs analysis of clinical trial workforce across the VCCC and regional Victoria including identifying the optimal modes of delivery of education and training for a diverse and dispersed workforce.
- mapping of clinical trial workforce training currently offered in Victoria to enable identification of gaps and unmet needs.

During phase 2, competency frameworks will be developed for research nurses and clinical trial co-ordinators. These will leverage existing frameworks developed in the UK and the USA. The definition of and skills required for these roles differ between organisations, reducing the ability of organisations to share resources and work together. The competency frameworks will guide development and delivery of education and training programs.

Phase 2 will also involve bringing together the clinical trials workforce to facilitate shared learning and problem solving. Flexible platforms will be required to both connect the relevant sections of the clinical trial workforce and to provide "just in time" learning opportunities to a diverse workforce.

The needs analyses, mapping and competency frameworks will guide development and delivery of education and training programs in Phase 3.

Milestones

Milestones have been outlined for phases 1 and 2 of this program. Milestones for phase 3 will be developed during phases 1 and 2 once the needs analyses, mapping and competency frameworks have been completed.

Milestone	Date
Appointment of a steering group and agreement of its terms of reference	Q4 2017
Complete needs analysis	Q2 2018
Complete mapping of workforce and training	Q2 2018
Establishment of a competency framework	Q4 2018
Commence development and delivery of workforce training	Q3 2018

Measures of success

Measures of success for phases 1 and 2 will include:

- Completion of needs analysis.
- Establishment of a competency framework.

Measures of success for phase 3 will be specific to the training provided and will be developed alongside the training programs. Some general measures will include:

- Number of education and training programs developed.
- Attendance of education and training programs.
- Number of staff trained.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Clinical Trials Workforce Development Manager	1 FTE	$330,000	VCCC
Project officer	1 FTE	$240,000	VCCC
On-costs			
Salaries		$104,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Funding for phase 3- education and training delivery		$800,000	
Meetings and forums		$50,000	
Online learning platform development		$150,000	
External education and training providers		$100,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,819,000**	

Governance

The Development of Workforce Capacity and Capability program will have a Steering Group with appropriate educational and clinical trial expertise that reports to CETAC and CRAC. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the Steering Group will be a CETAC member. Working groups of appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

- Workforce development will build sustained capability through increased clinical trial activity.
- Once capability is expanded to meet the current gap between need and supply, fewer resources will be required to maintain the workforce.

Program 14: Metrics for Clinical Trial Participation

The VCCC will invest up to $570,000 in the development of metrics that not only measure system change, but can be used as evidence and levers for improvement of the clinical trial system, particularly to drive the system-wide cultural changes that will be required to achieve lasting outcomes.

The key elements of this program are:

- defining the value of clinical trials and developing metrics that reflect this
- testing and validating the feasibility of collecting agreed metrics that encapsulate the value of clinical trials, and their potential to create perverse incentives

Context

Metrics have three roles in system change:

- Measurement of change
- As evidence for advocacy for changes in policy or process
- Levers to drive change

The key risk in developing metrics, particularly in terms of their use as a lever, is the creation of perverse incentives. In this scenario, the system improvement initiatives drift so that the focus is improvement of the metric rather than improvement of the system to achieve the original objectives. In contrast, well-constructed, robust metrics can contribute towards positive system change when teamed with clear objectives that have buy-in from stakeholders.

Rationale

While all levels of government, clinicians, researchers and cancer patients all support improvement of the cancer clinical trials system, it is less clear how to achieve this or how to know when it has been achieved.

Improvements in participation, impact and innovation in clinical trials cannot be demonstrated unless new metrics are developed and agreed.

Leverage and synergies

The program will seek to leverage the metrics that are already collected, particularly by the Cancer Trials Management Scheme (CTMS) program at Cancer Council Victoria. The program will also be able to leverage the large body of work being undertaken at the national level including evidence synthesis, environment scanning and consensus building.

Connectivity with other priority programs

All clinical trial-related programs.

Goals/desired outcomes

A suite of metrics agreed across the VCCC to allow improvements in participation, impact and innovation in clinical trials to be demonstrated.

Timelines

This program will commence in Q4 2017 to coincide with the Clinical Trials Metrics Roundtable being co-convened by Cancer Council Victoria and the Victorian Cancer Agency. It is envisaged that testing and validating of agreed metrics will commence in Q1 2019.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	Q4 2017 (development) Q1 2019 (testing)												

Activities

The activities that will be conducted as part of this program include:

- working closely with key stakeholders to gain consensus on the most useful, meaningful and practical metrics to measure trial numbers, participation, timeliness, cost-effectiveness, quality and impact
- developing and testing agreed metrics within selected VCCC sites
- testing the feasibility and cost-effectiveness of data collection.

Milestones

Milestones have been outlined for the first year of this program encompassing work to gain consensus on clinical trial metrics. Milestones for 2019-2021 will be developed that will focus on collection and analysis of data for agreed metrics.

Milestone	Date
Appointment of a steering group and agreement of its terms of reference	Q4 2017
Commence engagement with key stakeholders within and external to the VCCC	Q4 2017
Convene/ join stakeholder group(s) to develop consensus	Q4 2017
Complete literature review and evidence synthesis	Q2 2018
Complete qualitative research to test usefulness and value of consensus metrics	Q4 2018
Testing feasibility and cost of access and/or collection	Q1 2019

Measures of success

Measures of success will include:

- Engagement of stakeholders as measured by attendance at meetings, forums etc
- Agreement on metrics to be tested and validated
- Number of metrics agreed to be valuable to measure trial numbers, participation, timeliness, cost-effectiveness, quality, impact and innovation
- Number of metrics that are determined to be feasible and cost-effective to collect

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Data analyst- testing and validation of metrics	0.5 FTE 2.5 years	$150,000	VCCC
On-costs			
All salaries	20%	$30,000	
Consultancies			
Qualitative research eg interviews, surveys, focus groups		$80,000	
Direct Research Costs			
Enabling Facility Costs			

Other Costs			
Data collection at VCCC sites		$250,000	
Meetings and events		$10,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		$565,500	

Governance

The Metrics for Clinical Trial Participation program will have a Steering Group with appropriate scientific expertise that reports to CRAC. The Steering Group will include at least one expert member- patient perspective. Governance and reporting will then be as outlined under the section entitled 'SRP Governance'. One member of the steering group will be a CRAC member. Working groups of appropriate representation and expertise will be convened when required.

Opportunities to enhance sustainability

- Once metrics are developed and agreed, they become a core part of how clinical trials are measured.
- In the future, the costs of standard metric reporting will need to be shared between those requiring the reports and those conducting the trials.

Section C: Translational research enablers

Five programs have been developed that focus on enabling the later stages of translation. These include:

- programs that enable health services research that will underpin changes in policy, clinical practice and service delivery and lead to improvements in the quality, efficiency, cost and equity of cancer services.
- programs that directly address translation of knowledge, and integration of research and education, into clinical care.
- education and training programs to support and facilitate dissemination of new evidence and adoption of new practices.

These five programs are:

- Program 15: Research & Education Lead program
- Program 16: Building Analytical Capability for Health Data-driven Research
- Program 17: Building Nursing Research Capability
- Program 18: Communities of Practice
- Program 19: Masters in Cancer Sciences

Program 15: Research & Education Lead program

The VCCC will invest around $4.1 m to systematise collaboration across the VCCC and to operationalise the idea of integration of research, education and clinical care.

The key elements of the program are:

- Build leadership and networks for tumour streams and selected cross-cutting themes across the VCCC
- Expansion reach of the tumour stream/cancer theme through online learning programs.

Context

The Research and Education Lead program began as a pilot in July 2015 with the aim of building leadership capacity and capability within the framework of tumour streams and cancer themes to work across all the VCCC partners.

Rationale

- The program addresses the single biggest risk to the success of the VCCC- that partners won't work together effectively - through normalisation of system-level collaborative activities across VCCC partners
- The Research and Education Leads will champion the VCCC Strategic Research Plan in relevant areas.
- The 2009 Business Case for the VCCC articulated the vision for why the VCCC was created and included a number of elements that are addressed under the Research and Education Leads program such as:
    - integration of cancer research, education and patient care
    - collaboration
    - sharing of ideas and knowledge, which will in turn translate into improved patient outcomes
    - translating results from basic and clinical research to a high quality, seamless patient journey
    - bringing together specialist clinical cancer care and research to create synergies between research and clinical practice
    - quickly implementing the latest local and overseas advances in cancer diagnosis and treatment
    - ensuring best practice by advanced training of cancer clinicians
- The program addresses a significant proportion of the potential priorities for the VCCC partnership that have been frequently cited in consultations and needs analyses, such as:
    - optimal integration of research, education and clinical care
    - use sub-speciality tumour streams as a focus for multidisciplinary research programs
    - dissemination and adoption of new evidence into improved routine practice
    - identifying, promoting and reviewing world's best practice in patient care, education, training and research
    - strategies for disseminating new research evidence
    - thinking about how to tackle the big problems
    - facilitating shared education and training (in cancer specific and generic areas) across member organisations to bring together complementary strengths of institutions and skills of individuals

- using enabling technologies to ensure education and training is accessible to all staff across member organisations

Leverage and synergies

- The successful pilot of the Research & Education Leads program over two years.
- Existing research and education activities at individual VCCC partners.
- The education and training aspect of the program leverages UoM learning platforms.
- The existing VCCC Leaders Program – a bespoke program designed and run by the Melbourne Business School in partnership with the VCCC – coaches key research, education and clinical care staff in customised leadership skills to enable participants to lead more effectively within an alliance environment.

Connectivity with other programs

The Research & Education Leads program provides key enablers for all other programs.

Goals/desired outcomes

The overarching goal for the Research and Education Leads program is for the VCCC partners to work together better. The program is a vehicle through which this can occur and aims to achieve the following outcomes:

- better leadership and strategic direction for the research and education/training aspects of the tumour stream or cancer theme
- integrating research, education and clinical aspects of tumour streams or cancer themes, so as to support optimal patient care
- embedding international and local research and evidence into clinical practice
- increasing the impact, breadth and depth of research relevant to the cancer theme across the VCCC through promotion of multi-site, multi-disciplinary, collaborative research that correlates with research excellence and impact
- adding value to education and training programs that underpin excellence in clinical care and research
- facilitating better use of integrated research and clinical data across VCCC partners
- enabling multi-site clinical trials.

Timelines

The program has been running since July 2015, and will continue until Q3 2020

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	Continuing												

Activities

The Research & Education Leads program is already established with three pilots (Haematology, Melanoma and Skin Cancer, Primary Care Integration) having run for over two years and a second tranche (Lung, Gastrointestinal Tract, Cancer Nursing) for 12 months.

Expansion of the Research & Education Lead program to include six tumour new streams will create a critical mass of researchers, educators and health care professionals in 12 tumour streams/cancer themes.

The Research and Education Leads Program is designed to investigate, test, evaluate and improve how knowledge translation and collaboration is done with the aim of expanding collaborative research and improving integration of research and education into clinical care. The program has three broad phases:

i. Development of an evidence-base to inform and support collective planning through a mapping exercise and engagement with relevant healthcare professionals, researchers and educators across all partner sites
ii. Development of a VCCC-wide consensus direction, that is agreed and strategic, for the tumour stream or cancer theme with a focus on creating new networks and other enablers for knowledge transfer
iii. Focus on outward-facing knowledge translation to integrate research, education and clinical care and facilitate practice change across the VCCC.

Activities in the first phase of the program aim to develop an evidence-base that supports strategic targeting of new activities so as to improve performance in cancer research and education/training, and optimally integrate research and education/training with clinical care to improve patient outcomes. These include:

- "mapping" education and research activities for each of the three pilots across all the VCCC partner organisations through
    - semi-structured discussions with key individuals and/or groups across a range of professional levels and fields
    - observational data gathered from seminars, multidisciplinary meetings and other educational meetings
    - baseline data from the VCCC Research Census (eg research grants), bibliometric analyses of VCCC publications and citation impact and VCCC clinical audit data.
    - consultation with key individuals and/or groups that has been shown to result in significant, but difficult to measure, engagement of researchers and healthcare professionals across the VCCC

Activities in the second phase of the program aim to develop a VCCC-wide consensus direction for research and education in each tumour stream or cancer theme, that is agreed and strategic, and to obtain feedback on applicability, feasibility and mechanisms for roll-out. These include:

- convening a strategic group with the ability to come together to think collectively, to identify activities and processes that are better tackled as a group than by individual organisations, and to identify the most important clinical challenges that could be a focus for new research. The pilots demonstrated that a shared understanding of the environment in which they operate (provided by the mapping in phase 1) is a prerequisite for this collective thinking and collaborative activity.
- development of new peer networks and other enablers for knowledge transfer within the tumour stream or cancer theme
- conducting effective and innovative research meetings or educational activities that support continuing professional development of the workforce

Activities in the third phase of the program aim to normalise collaborative and multi-disciplinary research across organisations and to facilitate practice change across the VCCC partnership. These activities are still being finalised but may include:

- developing mechanisms that facilitate sharing of new research-derived evidence, data and knowledge
- identifying priorities for research-enabling infrastructure

- promoting collection, linkage and sharing of health, clinical and research data that is an enabler for research
- identifying strategies to increase the number of patients who participate in research
- participating in the development of a framework to promote multi-site clinical trials and increase the impact of clinical trials
- harmonising educational activities across the VCCC
- developing ethical and cost-effective mechanisms that increase availability of patient specimens and data as an enabler for research
- development of a portfolio of high quality research projects for trainees across the VCCC partnership to address the specific training needs in research skills for junior clinicians and clinician-scientists
- further development of the leadership roles for each Lead to work towards collectively forming a senior advisory council for the VCCC partnership, and to act as a key opinion leaders to promote and/or advocate for the tumour stream or cancer theme to industry, government and philanthropy

Research and Education Leads will have key roles in a number of programs that require leadership and expertise. These programs are:

- Investigator-initiated Trial Capacity Building: participation in the VCCC Clinical Trial Development Hub
- Precision Oncology: contribution of clinical judgement to the system to request genomic assays for those patients who are most likely to benefit
- Metrics for Clinical Trial Participation: expert opinion on the most useful, meaningful and practical metrics to measure trial numbers, participation, timeliness, cost-effectiveness, quality and impact
- Building Analytical Capability for Data-driven Research: participation in the Data-driven Research Hub

Milestones

Milestones for appointment of new Leads are outlined. Because the Leads commence their roles at different times, milestones for each phase of work are expressed from time of appointment. Milestones for the third phase of the program will be developed by consensus during the second phase.

Milestone	Date
Appointment of a steering group and agreement of its terms of reference	Q4 2017
Recruitment of two new Leads	Q2 2018
Recruitment of four new Leads	Q3-Q4 2018
Report on mapping of education and research activities across all the VCCC partner organisations	12 months post-appointment
Agreement on at least one strategic direction for the tumour stream or cancer theme	18 months post-appointment
Agreement on the most important clinical challenges for the tumour stream that could be a focus for new research	18 months post-appointment
Conduct of an effective and innovative research meeting or educational activity	1 per year

Measures of success

Measures of success will be tailored for each tumour stream or cancer theme.

Measures of success that are assessable in the short term will primarily be to do with development of an evidence-base to inform and support collective planning. These include:

- numbers of research and education opportunities, strengths, exemplars needs and gaps across all partners identified through mapping
- measures of engagement such as numbers of meetings/ activities, numbers of participants and level of engagement as measured by response to qualitative surveys
- measures of impact of research meetings or educational activities

Measures of success that are assessable in the medium-long term will primarily be to do with developing a VCCC-wide consensus direction, that is agreed and strategic. These include:

- numbers of clinicians, researchers and educators in each tumour stream network
- measures of consensus on strategic direction and important clinical challenges
- number of education/training modules that have been converted to an on-line format
- numbers of collaborative grant applications
- total grant funding in the tumour streams and selected cancer themes

Measures of success that are assessable in the longer term will include impact of leaders across all the VCCC partners, new research, education and/or clinical initiatives across VCCC partner organisations, quantitative metrics of research output, educational activities and facilitation of practice and/or policy change across the VCCC partnership.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Re-imbursement/ protected time for Leads	12 Leads, 0.1-0.2 FTE, 2-3 years	$2,180,000	Multiple partners
Program Manager	1 FTE x 3 x 2.5-3 years	$965,000	VCCC
Education Development Manager	1 FTE x 2.5 years	$235,000	VCCC
Data analyst	0.5 FTE 2.5 years	$115,000	VCCC
On-costs			
All salaries	20%	$263,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Education and event costs		$350,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$4,153,000**	

Governance

The Research and Education Lead program will be overseen by and report to the Executive Director and CRAC.

Program 16: Building Analytical Capability for Data-driven Research

The VCCC will invest approximately $1.3m in better use of existing health data for research.

The key elements of this program are:

- a platform that facilitates sharing of, and access to, VCCC and external cancer health data for research.
- building cancer health services research and data-driven clinical research.
- bringing together data sciences and clinical expertise.

Context

Barriers to better use of existing health data include inconsistencies in the type of data items collected and incompatibilities in the structure of data collected in different organisations. As a way of bringing data together, patient-level record linkage is flexible and cost-effective compared to data integration, however linkage creates complex and variable data structures that are more difficult to analyse. New research capability in data sciences, such as applying the methods developed for 'big data' analytics, will enable even unstandardised data to be better used while minimising misinterpretation.

Rationale

The principle behind this program is to accept the current data environment and to test and validate approaches to making the most of retrospective health data that is already collected and stored electronically by the VCCC hospitals.

Rationales for investment in data-driven research include:

- Sharing, access and linkage of health data related and data-driven research have been one of the most frequently cited potential priorities for the VCCC partnership
- Independent evidence that collection, access, sharing, linkage and analysis of health data is a capability gap for Australian health and medical research came from the recent Australia-wide consultation conducted by the Australian Medical Research Advisory Board
- As a pre-existing collective that is larger than any single organisation, but is smaller and therefore more manageable than a State, the VCCC is an ideal ecosystem in which to test a model for access, sharing, linkage and analysis of health data for research.
- The VCCC is well positioned to build a platform for data-driven research as it has direct access to record-linkable data and to rich and deep clinical, costing and clinical registry data
- Government-held health data for research has, to date, not met the needs of many researchers.

Rationales for investment in cancer health services research:

- A systematic, academic program of outcomes-focussed health services research is one way of reducing the impediments to the latest advances being available for cancer patients
- Overseas experience has demonstrated that health services research has a significant influence on health policy and practice. The VCCC research censuses identified health services research as a gap in research capability across the VCCC
- Health services research was identified as a gap in the Australian health and medical research profile in the McKeon report
- In Australia, lack of integration across healthcare sectors is widely cited as one reason for less than optimal health and wellbeing outcomes. Until now, it has not been possible to extract detailed data from primary care, therefore care given to cancer patients by General Practitioners and other primary care health professionals has been invisible to health services research that seeks to improve evidence-based and cost-effective care.

Leverage and synergies

This program capitalises on preliminary work to build a data platform for health services research and leverages the following existing capabilities:

- UoM academic expertise in health informatics, health data analytics, epidemiology, statistics, health services research focussed on the primary care sector, implementation science and health economics and planned investment health data-driven research.
- GRHANITE software for large-scale data acquisition of health data, encryption of identifiers for health data and privacy-preserving data linkage technologies developed by UoM.
- Investment in a Chair of Cancer Health Services Research (UoM).
- A funded demonstration health services research project.
- BioGrid Australia's legal status to receive identified data for the purposes of data linkage
- Existing, robust data governance systems at BioGrid Australia including: separation of identifiers and health information, federated data sharing so that each hospital remains the custodian of its own data, data access systems that permit researchers to access only de-identified data, secure retention of identifiers so that data can be linked to new datasets as they are acquired and data can be updated and/or refreshed over time without having to repeat the linkage.
- Existing capability for accurate data linkage - both deterministic and probabilistic methods (BioGrid and Victorian Cancer Registry).

This program leverages existing electronic health data including:

- Administrative (episode) data in electronic form and record-linkable at the patient level in VCCC hospitals.
- Rich and deep clinical, costing and other clinical registry data from the VCCC hospitals.
- Patient outcomes survey data (Patient Recorded Outcomes Measures (PROMs) data) for 3000 VCCC patients.
- Definitive diagnosis data (that enables identification of cancer patients within VCCC hospital data through patient-level record linkage without relying on ICD codes from hospital datasets) within the Victorian Cancer Registry dataset.
- Existing linkage to National Death Index data (which provides important patient outcome data that is not always readily available to clinicians and researchers) through the Victorian Cancer Registry.
- Existing record-linkable dataset from over 500 General Practices representing over 2 million patients contributed by the National Prescribing Service.

Connectivity with other priority programs

- Research and Education Leads program: systems that facilitate/support collaborative and multi-disciplinary research to bring together data science and clinical expertise.
- Building Nursing Research Capability: health services research
- Building Connectivity program: patient reported outcomes and experiences research special interest group (under Communities of Practice).
- Registry Trials program: clinical registries.

Goals/desired outcomes

- Establishment of a platform for sharing and accessing health data that can grow, is flexible and meets researchers' needs

- Increased health data sciences research, including health services research, health economics and patient outcomes-focussed research, with impact on patient outcomes and efficiency of health services, and with influence on health policy and practice.

Timelines

Work has already commenced for this program, and will continue until Q3 2020.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Platform development	Continuing												
Data-driven research hub	Q1 2018 (development) Q4 2018 (operation)												

Activities

Activities that will be conducted to build a platform for sharing health data include:

- Complete and maintain the linked VCCC administrative datasets.
- Add and link costing datasets from VCCC hospitals to the platform.
- Add and link primary care clinical data from NPS and other sources.
- Add and link Victorian Cancer Registry data.
- Add and link relevant VCCC clinical datasets.

A VCCC data-driven research hub will be established to reduce costs and improve access to health data for researchers. The hub will:

- Provide expertise on and access to health data for researchers during the research project. concept and development Phase.
- Provide streamlined access to linked internal and external datasets.
- Build academic capability in analytical and data sciences that underpin data driven research.
- Bring together clinical and data science expertise to enable key health services research-related questions to be answered.

Milestones

Milestones have been outlined for the first 12 months of this program. Once the key personnel are appointed and the Data-driven Research Hub established, milestones for 2019- 2020 will be identified for health services research.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Complete linkage of first primary care dataset	Q4 2017
Proof of concept test for linkage of VCR (and associated VDI) data	Q4 2018
Progressive linkage of hospital datasets and registries as they become available	Updated reports 6 monthly
Recruitment of Data-driven Research Hub manager	Q1 2018
Launch Data-driven Research Hub	Q4 2018
Recruitment of data scientist	Q3 2018

Measures of Success

Measures of success assessable in the short term will be numbers of datasets linked and quality of data linkage.

Measures of success that are assessable in the medium-long term will be the establishment and development of the Data-driven Research Hub including:

- measures of engagement such as numbers of meetings/activities, numbers of participants and level of engagement as measured by response to qualitative surveys.
- numbers of new health services research questions workshopped.
- numbers of new clinical datasets and registries contributed to the platform.

Measures of success in the longer term will be numbers of new collaborative and cross-disciplinary research projects, as well as with research funding, numbers of publications and research impact as measured by citations and changes to policy and/or practice.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Data-driven Research Hub Manager	1 FTE	$330,000	Partner
Data Scientist	1 FTE	$220,000	Partner
On-costs			
All salaries		$110,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
BioGrid Membership	$27,516.50 pa x 3 years	$82,550	
Database technical specialist - BioGrid	1 FTE	$357,100	
Ethics specialist and project management- BioGrid	0.4 FTE 2 years	$97,000	
Data linkage- Victorian Cancer Registry		$100,000	
Other Costs			
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,341,650**	

Governance

The Building Analytical Capability for Data-driven Research program will have a Steering Group with appropriate clinical and data sciences expertise, as well as expertise in the patient perspective (consumer representation). The Steering Group will report to CRAC. One member of the Steering Group will be a CRAC member. Governance and reporting will be as outlined under the section entitled 'SRP Governance'.

Opportunities to enhance sustainability

- Once built, maintenance of the data platform will have decreased associated costs.
- Access to data will be cost free for researchers.
- High quality health services research is likely to attract research grant funding.
- The Faculty of Medicine, Dentistry and Health Sciences (UoM) strategy is looking to invest in health informatics/ health data-driven research.

Program 17 Building Nursing Research Capability

The VCCC will invest approximately $1 million to develop cancer nursing research capability that has potential to enhance patient care, health outcomes and health services efficiency.

The key element of this program is the development of research literacy and capability among cancer nurses, centred around a VCCC nursing research innovation hub, that will result in greater nurse-led clinical research activity across the VCCC, Victoria and Australia.

Context

A knowledgeable, research-enabled and research-active nursing workforce is a fundamental component of a truly comprehensive cancer centre (CCC). However, both internationally and locally, the essential contribution of nursing knowledge to delivering the practice, education and research objectives of a CCC has largely been overlooked. With a commitment to the growth and development of academic cancer nursing, the VCCC will set itself apart as a world leader.

Rationale

The majority of a cancer patient's time in a healthcare facility is spent with nurses, in both inpatient and outpatient settings, including follow-up clinics and day therapy units. In addition, nurses form the largest component of the health workforce in metropolitan, regional and rural areas. Therefore, there is considerable potential for nurses to positively impact cancer patient care and health outcomes through rigorous research activity.

Patient-centred issues are the domain of nurse-led research, as distinct from other medically-based research fields. Areas such as access to and equity of care, symptom and side-effect management, efficient models of care and post-treatment care and wellness are under-researched, but offer considerable opportunity to improve patient experience and outcomes, as well as to enhance system efficiency.

Senior nursing staff in all VCCC hospitals recognise that nursing research capability is an area of unmet need. Barriers to nurses' participation in research are well-recognised. There are few PhD-prepared or active postdoctoral-level cancer nursing researchers in Victoria. Currently, nurse-led research is typically limited in scale, and often has low impact.

At the same time, nurses demonstrate daily their keen clinical insight and their capacity to question practices that can form the basis of research studies. With appropriate guidance and support, such research can be impactful. Therefore, academic-led nursing research support by the VCCC will harness untapped potential and transform nurse-led research in Victoria.

Leverage and synergies

- Established network of Professors of Nursing across VCCC clinical and academic partners
- Content from a Clinical Research Fellowship program (UoM and PeterMac) that was targeted to the needs of clinical nurses wishing to develop research capability to innovate in nursing practice.
- Existing cancer nursing education and research training programs such as the Graduate Certificate, Master of Nursing Science and Master of Advanced Nursing Practice (UoM).
- Content from the Masters of Cancer Sciences subjects such as Cancer Research, Cancer Nursing and the capstone minor research thesis.
- Existing cancer nursing research expertise across VCCC.
- Existing collaborations through the VCCC Cancer Nursing Research & Education Lead role and additional honorary research appointments at PeterMac, RMH and ONJCWC at Austin Health.

Connectivity with other priority programs

- Masters of Cancer Sciences: deepening cancer knowledge and strengthening research skills among nurses.
- Building Analytical Capability for Health Data-driven Research: access to data for health services research projects in cancer nursing.
- Clinical Trial Workforce Capacity and Capability: upskilling nurses in research methodology leading to greater nurse understanding of, and capacity to be, an investigator for clinical trials.

Goals/desired outcomes

Development of a nursing research innovation hub. The hub is the core enabler that will:

- create an incubator for developing new nurse-led research programs.
- grow academic leadership in nursing research.
- create a point of connectivity and research mentorship for nurses from across Victoria.

Development of workforce competence and capability to:

- increase numbers of and upskill nurses in implementation science skills to integrate evidence into routine practice.
- increase numbers of and upskill nurses who work with people affected by cancer to develop and lead research using a number of methodologies including clinical trials, comparative effectiveness research and health services research.
- upskill key cancer nurses in advanced research skills that will allow them to contribute to and lead national and internationally competitive grants.
- increase numbers of PhD-trained nurse clinicians who have the skills to be research leaders.

In the longer term, the goal is to develop a research culture among VCCC cancer nurses and through this to systemically improve hospital-based service delivery and consequently improve patient experience.

Timelines

This program will commence with the appointment of a Program Manager in Q1 2018. Because the VCCC nursing research innovation hub is a novel approach to developing nursing research, it will take approximately 6 months to develop, and will therefore begin operating in mid-2018.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Nursing research innovation hub	Q4 2017 (development) Q3 2018 (operation)												
Nursing research educational modules	Q1 2018 (development) Q4 2018 (available)												

Activities

Activities that will be undertaken to establish the VCCC nursing innovation hub include:

- formalising an agreed network of Professors of Nursing and nurse clinician-researchers from across VCCC clinical and academic partners to form the core of the nursing research innovation hub.
- building a structure and network to enable training and mentorship of cancer nurses conducting patient-centred and health systems research.
- establishing a process and criteria to accept and assess applications for seed funding for nurse-led research projects.

- appointment of program manager who, under the direction of the VCCC Research & Education Lead in Cancer Nursing, will be responsible for:
    - coordination of the network of Professors of Nursing and nurse clinician-researcher research mentors.
    - operational activities relating to access to the hub by nurses.
    - co-ordination of access to educational programs.
    - promotion of the hub.
    - evaluation of the structure and function of the hub for continuous improvement.

Once established, the VCCC nursing research innovation hub will provide:

- mentorship of cancer nurses conducting patient-centred and health systems research through a network of academic nurses.
- collaborative research that builds nurse-led research capability across VCCC partners.
- guidance for development of research projects.
- support for the unique training needs of the nursing sector.
- repurposing and making accessible existing cancer nursing research education materials.
- facilitation of cross-institutional collaborations in ways that would not be achievable by individual hospitals.
- create a point of aggregation for nurse-led cancer research to maximise impact.

Milestones

Milestones have been outlined for the first 12 months of this program. Once the key personnel are appointed and the nursing research innovation hub established, milestones for 2019- 21 will be developed that will focus on nurse-led research.

Milestone	Date
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Establish governance oversight, operational and supervision structure for the nursing research innovation hub.	Q1 2018
Appoint Innovation Hub Program Manager	Q1 2018
Develop an evaluation framework for the Innovation Hub	Q2 2018
Repurpose content and modes of delivery for Innovation Hub nursing research education materials that interface with existing tertiary cancer nursing research modules/programs	Q2-Q3 2018
Launch the VCCC nurse-led research Innovation Hub	Q3 2018
Commence the first series of Innovation Hub initiatives	Q3 2018
First Annual VCCC Nurse-led Research Symposium	Q1 2019

Measures of Success

Measures of success during the development of the nursing research innovation hub will initially be measures of engagement such as numbers of meetings/activities, numbers of participants, and level of engagement as measured by response to qualitative surveys.

Measures of success in the medium to long term will include:

- numbers of nurses mentored/ supervised.
- numbers of nurses bringing forward research ideas to the hub.
- number of new nurse-led research projects commenced.
- number of multi-site, collaborative research projects commenced.
- number of cancer nurses undergoing training.

- numbers of nurses enrolling in research higher degrees.
- numbers of PhD-trained nurse clinicians.
- number of presentations at conferences by cancer nurses.
- number of nurse-led clinical trial.

Measures of success for which change will be seen in the longer term will be relate to research funding, numbers of publications and research impact as well as clinical impact on patient experience and outcomes.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Program manager	1 FTE	$330,000	Partner
Statistician	0.4 FTE	$140,000	Partner
On-costs			
Salaries		$94,000	
Consultancies			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Seed funding for research projects		$300,000	
Education and training activities	3 years	$90,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$990,000**	

Governance

The Nurse-led Research Workforce Capability Building program will have a Steering Group with appropriate nursing research and educational expertise, as well as consumer and VCCC member representation. The Steering Group will be chaired by the VCCC Research & Education Lead in Cancer Nursing and will report to CRAC. One member of the Steering Group will be a CRAC member. Governance and reporting will be as outlined under the section entitled 'SRP Governance'.

Opportunities to enhance sustainability

- The nursing research innovation hub will provide a sustainable model for sharing knowledge, and developing collaborations and expertise among nurses across the VCCC and Victoria.
- The nursing research innovation hub will actively support and train the nurse research leaders of the future.
- While face to face research training is important, an online platform to support and enable nurses to connect will increase the sustainability of mentoring and research supervision.
- Funding for nurse-led research from commercial or philanthropic sources or through competitive grants.

Program 18: Building Connectivity

The VCCC will invest around $620,000 to build connections and networks across the VCCC partners that will facilitate groups with common interests working together.

The key elements of the Building Connectivity program are:

- to establish groups in three initially prioritised areas of focus.
- use lessons from these initial areas, plus a review of international best practice in building connectivity within partnership organisations, to develop the framework, processes and resources required to enable connectivity across the VCCC.

Rationale

Building connectivity, and facilitating collaboration and partnerships, underpins the VCCC organisational remit. As an alliance organisation, the VCCC's ability to understand and consistently implement effective processes to build connectivity will be central to efficiently integrating research, education and clinical care to maximise patient outcomes.

Consultations across the VCCC alliance have consistently highlighted the need for a co-ordinated approach to help bring together like-minded individuals. By facilitating such connections, researchers and clinicians across the partnership will have the opportunity to share, learn, identify and solve problems and ultimately to improve outcomes for patients. Effective connections and communication among groups with similar or complementary interests will be central to enabling the VCCC partnership to realise its potential, through ensuring the best minds in cancer care are working together.

The critera for prioritising areas of focus include:

- potential for significant collaborative gain or capacity building through working together.
- alignment with work in other priority programs.

Leverage and synergies

- The currently fragmented but high-level existing expertise in patient outcomes research, bioinformatics and PET across the VCCC.
- The successful science-clinical preceptorship program established by WEHI and RMH.

Connectivity with other priority programs

- Research & Education Leads program: this program of developing networks and tailored professional development activities in selected tumour streams/ cancer themes has provided valuable lessons in how to build connectivity within the VCCC.
- The Building Connectivity program will eventually underpin all programs and VCCC activity.

Goals/desired outcomes

The key goals of the program are:

- to build connectivity and networks that reduce organisational boundaries to enable system-level collaboration.
- to build the internal intellectual capital and processes to enable effective connections between organisations, disciplines and research specialities.

Timelines

Although some initial areas for support have been identified, the program of work within these areas has not been defined at this stage. The program will begin in Q4 2017 in a phased approach.

Phase 1 will involve evidence gathering and defining the program of work for the prioritised areas of focus.

Phase 2 will involve the implementation of the agreed program of work for the prioritised areas of focus (including resource development where required).

In phase 3, the learnings from international best practice (Phase 1) and the prioritised focus areas (phase 2) will inform the best practice processes to enable organisationally-tailored connectivity for new and emerging groups.

This program will be evaluated on a 6-12 monthly basis to enable continuous improvement.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Phase 1: Evidence gathering	Q4 2017												
Phase 2: Implementation of first groups	Q3 2018												
Phase 3: New and emerging groups	Q2 2019												

Activities

This program will provide support to identified groups (and new and emerging areas) that have potential for significant collaborative gain through working together.

Activities in phase 1will include:

- supporting the connection of the initial groups and identifying the aims of each group, its membership, group leaders, planned activities and the preferred modes of communication
- consultation with potential new and emerging groups to assess the potential for collective gain if they were better connected.
- identification of resources and/or infrastructure required to address identified group needs and enhance connectivity.
- exploration of best practice in building connectivity within alliance organisations.

Activities for phase 2 will be developed based on the outcomes from phase 1 but will include at a minimum:

- providing support for groups to deliver face-to-face activities (eg targeted professional development, forums, preceptorships).
- developing resources and/or infrastructure where required (e.g. mentoring resources, IT enablers) to address identified group needs and enhance connectivity.

A number of types of resources and/or infrastructure will be tested for utility in the VCCC organisational context. Although face-to-face interactions are highly valued, the program will also explore other modes of communication that will extend reach and enhance sustainability.

Activities in phase 3 will focus on new and emerging groups.

- Although the program will focus on the initial three groups, it will have the capacity to remain responsive to new areas to generate research collaborations or impact clinical practice across and beyond the alliance. These areas will be identified via ongoing consultations with VCCC partner organisations throughout the course of the program.
- Learnings from phase 1and phase 2 will inform phase 3 activities that will utilise best practice processes to enable organisationally-tailored connectivity for new and emerging groups.

Milestones

Milestones specific for different groups will be developed once a plan of work has been agreed.

Milestone	Date
Phase 1: Evidence gathering	
Appointment of a Steering Group and agreement of its terms of reference	Q4 2017
Complete consultation with prioritised groups that have a need and potential significant collaborative gain through working together but require some support.	Q2 2018
A framework to guide best practice in building connectivity within alliance organisations	Q2 2018
A report exploring platforms for connectivity within multi-site collaborative alliances within the health sector.	Q2 2018
A plan for Phase 2 developed and agreed	Q2 2018
Phase 2: Implementation	
Three prioritised groups established	Q3 2018
Establishment of resources or infrastructure required to assist priority groups to connect and learn in accessible ways (e.g. mentoring resources, IT enablers).	Q4 2018
Phase 3: New and emerging groups	
Establishment of new and emerging groups	Q2 2019

Measures of success

Measures of success for phase 1:

- Numbers of groups that proceed to Phase 2.

Measures of success for phase 2:

- Measures of engagement such as numbers of meetings/ activities, numbers of participants and level of engagement as measured by response to qualitative surveys.
- Number of groups that achieve the goals or outcomes that they define.
- Number of groups that continue beyond 12 months.

Measures of success for phase 3:

- Number of new and emerging groups that approach the VCCC for assistance with connectivity.
- Number of new and emerging groups established.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Program Manager	0.5 FTE 0.75 years 0.8 FTE 2.25 years	$239,250	VCCC
On-costs			
Salaries		$47,850	
Consultancies			
IT consultancy to review and explore platforms for connectivity including current capacity, previous		$10,000	

connectivity projects, best practice in multi-site connectivity			
Direct Research Costs			
Enabling Facility Costs			
Other Costs			
Forums, workshops etc		$150,000	
Funds available to develop resources and infrastructure to implement program – as determined through Phase 1		$125,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$617,100**	

Governance

The Building Connectivity program will be overseen by and report to the Executive Director and CRAC.

Opportunities to enhance sustainability

Once groups are established and the processes and structures to support them are in place, their need for direct support will taper.

Program 19: Masters of Cancer Sciences

The VCCC will invest approximately $600,000 in the Masters in Cancer Sciences to provide a contemporary, evidence-based education and training program for health professionals who care for patients.

The key elements of this program are:

- a fully flexible online elective program delivered through a combination of on-line courses, webinars and interactive digital workshops.
- a nested program that can provide qualifications at the Specialist Certificate, Graduate Certificate and Masters level.
- a multidisciplinary program that includes cancer clinicians from the fields of surgery, radiation oncology, medical oncology, haematology, nursing, allied health and other health professions.

Context

The use of enabling technologies for online learning modalities has increased accessibility to a national and international audience, broadening the reach, diversity of the participant group and marketability of the programming.

Rationale

The Master of Cancer Sciences will be the first cancer-specific, multidisciplinary and wholly online Masters program of its kind offered in Australia. Internationally, there is only one program from Newcastle University, UK that is equivalent. This represents a tremendous opportunity for the VCCC to be positioned as a centre for excellence in cancer teaching and learning. Graduates of the Master of Cancer Sciences and its nested programming will possess an unprecedented breadth of integrated cancer knowledge and skills, and therefore be well positioned to contribute to the development of a world-class cancer workforce.

Postgraduate education and training has been consistently identified as a need across VCCC partners, including an Activity and Capability census in 2011, Research Higher Degree study into research training experience in 2012-13 and Census of Leadership Development in 2013. The census found that:

- professionals in a cancer-specific setting expressed a desire to integrate their knowledge with broader fields, while those in cancer-related settings expressed a desire to participate in cancer-specific programs.
- health professionals wanted a program through which best-practice approaches for cancer care, research and education were addressed.
- there was a desire to increase intellectual collaborations and knowledge transfer between multiple disciplines in the cancer context.
- there was a strong commitment by all members in the development, implementation and participation of educational activities.

A number of other rationales for investment in building trial group capability were identified including:

- The program aligns with the VCCC strategic objective to be the leading national and regional centre for cancer education and training.
- The program aligns with the VCCC strategic objective to create a skilled, high calibre, sustainable workforce in Victoria to meet the demands of future cancer control.
- This program is a requirement of the VCCC Core Funding and Strategic Research Plan Funding Agreement 2016-2020 that must be initiated by October 2020.

Leverage and synergies

- The intellectual critical mass within the VCCC alliance.
- GO Melbourne expertise, M Space (previously UoM Commercial), the Learning Management System and library facilities at UoM.
- Graduate Online Melbourne support and incentive funding grant ($140,000 + in-kind support) to support staffing and production costs including course convenors, subject development coordinators, Educational Development Manager, thesis supervisors, examiners and markers.
- The Learning Environments team at the UoM, who support the development of any additional programming that will be generated from the Master of Cancer Sciences eg. online learning, MOOCs etc.
- Revenue generation from the Masters and its nested programming, as well as any additional programming generated and commercial arrangements negotiated for their use.
- Subject content from other UoM postgraduate programs such as the Specialist Certificate in Clinical Research (Oncology), Master of Clinical Research, Master of Public Health, Master of Biotechnology and Master of Bioinformatics.
- Partnership with the Cancer Therapeutics CRC to develop an elective subject on Drug Discovery for the Master of Cancer Sciences program.
- Complementary expertise at Cancer Council Victoria to support the development of the Cancer in Society subjects.

Connectivity with other priority programs

- Research & Education Lead program: repurposed content and programming will align with the needs of the Research & Education Lead program.
- Development of Workforce Capacity and Capability program: there will be a number of subjects that will support the development of a clinical trials workforce eg. Cancer Research, Cancer Therapeutics, Drug Development and potentially the capstone minor research thesis.
- Building Nursing Research Capability: nurses will be encouraged and supported through scholarships to participate in the program. There will be a number of subjects that will support the development of a nurse-led research workforce eg. Cancer Research, Cancer Nursing and the capstone minor research thesis. Relevance of the other subjects will be accordance with the nurse's area of research.
- Building Connectivity program: the alumni from the Master of Cancer Sciences and its nested programming will form a community that could be enabled by this program. This community could unify to identify educational needs and best practice solutions within the VCCC.
- Alignment with the Comprehensive Cancer PhD program.

Goals/desired outcomes

- An education and training program that contributes to building the future cancer workforce for Victoria, and more broadly across Australia and internationally.
- Recognition for the VCCC as the pre-eminent cancer education and training institution in Australia.
- An upskilled cancer workforce with an increased understanding of evidence-based cancer care.
- A postgraduate program that is sustainable through on line delivery and fee-based cost recovery.
- Ability to repurpose content for ongoing professional development activities that may provide opportunities for additional revenue streams.

Timelines

Whilst some work has already commenced and the program delivery will continue beyond October 2020, for the purposes of the Strategic Research Plan funding, the program period is defined as October 2017 – October 2020.

Program element	Planned Start	2017	2018				2019				2020		
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	Continuing												

Activities and Milestones

Milestone	Date
Appointment of course co-convenors	Q2 2017
Appointment of subject development coordinators	Q2 2017
Establishment of program measures of success	Q4 2017
Commence subject planning and writing	Q1 2018

Subject development milestones:

Subject	2018				2019				2020				2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Foundations of Cancer	Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval			Deliver	Eval		
Cancer in Society		Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval			Deliver	Eval	
Cancer Therapeutics			Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval			Deliver	Eval
Cancer Research				Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval			Deliver
Cancer Diagnostics					Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval		
Survivorship, Supportive Care and Palliative Care						Plan	Write	Record	Post-prod	Deliver	Eval			Deliver	Eval	
Research thesis capstone							Plan	Write	Record	Post-prod	Deliver	Deliver	Eval		Deliver	Deliver
Cancer Prevention and Control							Plan	Write	Record	Post-prod			Deliver	Eval		
Drug Discovery								Plan	Write	Record	Post-prod		Deliver	Eval		
Cancer across the Lifespan									Plan	Write	Record	Post-prod		Deliver	Eval	
Cancer Nursing									Plan	Write	Record	Post-prod		Deliver	Eval	

Measures of Success

The measures of success will include:

- Number of participants enrolled in the Specialist Certificate, Graduate Certificate and Masters of Cancer Sciences.
- Conversion statistics from the Specialist Certificate to the Graduate Certificate and the Masters of Cancer Sciences.
- Retention and completion statistics for Specialist Certificate and Graduate Certificate.
- Number of Course Development Coordinators, Subject Development Coordinators, working party members, assessors and markers involved in the development and delivery of the program.
- Revenue generated by participating in other programming enrolling in individual subjects from Masters suite.
- Student Satisfaction Survey – measuring the quality of the program and teaching faculty from the perspective of the participants.
- Faculty Satisfaction Survey – measuring the quality of the program and support mechanisms from the perspective of the faculty.

Budget

	Type/Volume	Budgeted amount	Alliance member
Labour Costs			
Education Development Coordinator- oversee the project deliverables	1 FTE	$300,000	VCCC
Course convenor- expert advice on the content and structure of the course	0.2 FTE x 2	$240,000	Multiple partners
Subject development coordinators- advise and develop content relating to the specific subjects	$15,000 per subject x 10	$150,000	Multiple partners
Subject coordinators- delivery (Subject Development Coordinators will be given first right of refusal to adopt the delivery role)	$20K per subject delivered x 8 (prior to October 2020)	$160,000	VCCC
Supervision of major thesis	$10K per research capstone project (estimated 20 to Oct 2020)	$200,000	Multiple partners
Markers and assessors	9 subjects x 30 participants x $600 per subject	$162,000	Multiple partners
On-costs			
		$108,000	
Consultancies			
Other Costs			
UoM administration fee for all subject enrolments			
GO Melbourne for the development of the online resource			
Content development workshops x 4	$4000 per year x 3	$12,000	
Travel, taxi vouchers	$1000 per year x 3	$3,000	
Meetings and events	2 years	$10,000	
Communication, evaluation and consumer engagement activities	Per program share of total	$45,000	
Total		**$1,430,000**	

Revenue

	Type/Volume	Budgeted amount
GO Melbourne funding	Payments of CDCs and SDCs	$140,000
Revenue from enrolment in the course- based on 30 participants per year	$85,000 per subject x 4 subjects per year x 2 years	$684,000
Total		$824,000
Net total budget	**$1,430,000 - $824,000**	**$606,000**

Governance

The Masters of Cancer Sciences program has a Steering Group that comprises the Course Development Coordinators, each appointed Subject Development Coordinator, the Head, Education and Training Development and the Graduate Online Melbourne development team. Working groups for each subject will be convened and led by each Subject Development Coordinator for the period of the subject's development. The Course Development Coordinator is a member of, and reports directly to, CETAC. The Master of Cancer Sciences program also reports to CRAC.

Opportunities to enhance sustainability

- The Master of Cancer Sciences will be an online program supported by the University of Melbourne platforms. The UoM and VCCC will contribute to any start-up costs and share any revenue generated from the program equitably. It is envisaged that the Masters of Cancer Sciences will be a self-sustaining program i.e. fees will cover recurrent costs.
- The ability to repurpose content for ongoing professional development activities may provide opportunities for additional revenue streams eg. Charges for certification in the Cancer Survivorship for Primary Care Practitioners Massive Open Online Course (MOOC).
- The revenue from any commercialisation of this programming will be shared according to the contribution of the respective parties.

Action Plan

The 'Programs of work' section of this document outlines the strategy for achieving the goals of the funding agreement in the description of the investment that will be made, the key elements of each program and the goals/ desired outcomes. The description of each program also forms an action plan that details the activities that will be undertaken and the milestones and measures of success, as well as the budget.

The overarching governance arrangements and a corrective action plan process, which apply to all programs, are detailed below.

While the programs are grouped in the 'Programs of work' section, in practice they will all be highly interconnected. This connectivity is outlined under each program and also in Appendix C. The VCCC recognises the importance of these synergies and will take them into account within its project management framework. For this reason, although the VCCC received funding for this work under two agreements (the VCCC Funding Agreement 2016-2020 and the Schedule D amendment that describes funding for clinical trials), budgets have been constructed for the total funding allocation of $30m, rather than artificially assigning to either the $10M or $20M pools.

SRP Governance

The VCCC Executive Director (ED) has responsibility delegated by the VCCC Board for the implementation of the Strategic Research Plan. The ED is supported by the executive office staff. The VCCC governance structure provides oversight and support to the ED for the delivery of the programs articulated in this plan.

The VCCC Board of Directors meets every two months. The Board has an independent Chair and Deputy Chair appointed by the Victorian State Government, and comprises appointees of each of the partners of the VCCC alliance. The Board receives advice from standing committees that provide expertise in cancer research (Cancer Research Advisory Committee- CRAC), education (Cancer Education and Training Advisory Committee- CETAC), finance, risk and audit (Finance, Audit and Risk Committee- FARC), and the patient perspective (Cancer Consumer Advisory Committee- CCAC). Standing committees meet at the frequency required for operational needs. The rules outlining the interaction and objects of the VCCC are contained in a joint venture agreement which empowers the VCCC Ltd to manage the operations and activity of the partnership.

The SRP will be effectively managed and key decisions made appropriately through this governance structure. Robust, efficient structures, systems and processes will minimise risk and enable program delivery.

All four VCCC Board Committees will have active involvement in the governance and oversight of the SRP programs.

CRAC will be the Committee responsible for the ongoing monitoring and oversight of the SRP as a whole, to ensure it is progressing as intended, and to report to the Board on these issues. It will also provide advice to the ED. CETAC will also contribute to oversight of programs (see below). CRAC will receive regular reports from steering groups, and conduct formal reviews of each program on a rotating schedule.

CETAC will oversee the educational elements of each program and provide advice on pedagogy, evaluation of educational outcomes, any assessment requirements and the platform for supporting educational program delivery (LMS).

CETAC will have primary responsibility for the Masters of Cancer Sciences.

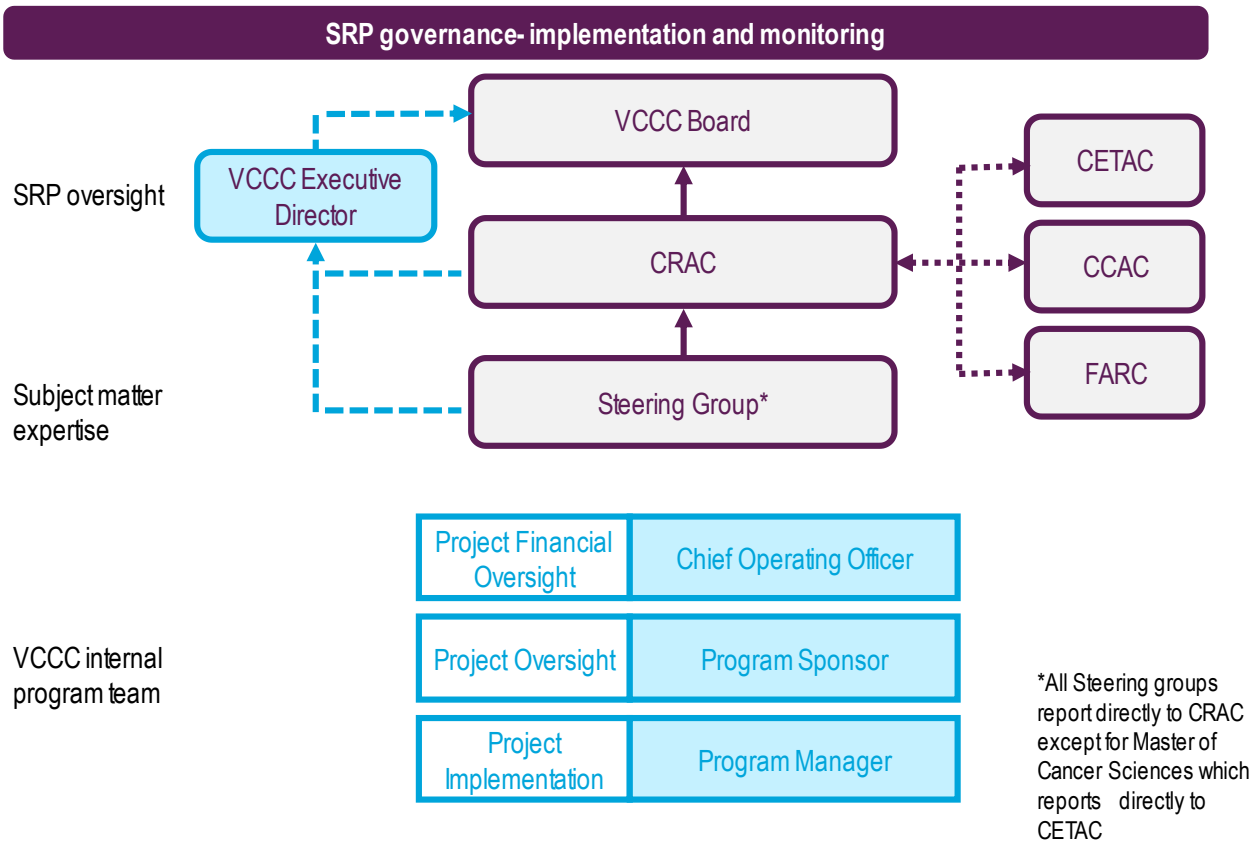
CETAC will have shared responsibility with CRAC for oversight of all programs and for review of the programs with significant educational elements, including:

- Development of Workforce Capacity and Capability
- Building Connectivity
- Research and Education Lead program
- Building Nursing Research Capability

FARC will be responsible for the monitoring and oversight of program budgets and risks.

CCAC will be involved in programs throughout their life-cycle from planning to outcomes and evaluation. The VCCC is developing a consumer engagement framework guided by the 'National Framework for Consumer Involvement in Cancer Control' published by Cancer Australia and Cancer Voices Australia. Consumer involvement in each program will align to the levels outlined in this national framework and is summarised in Appendix C.

Each program will be overseen by a Steering Group, providing subject matter expertise to support program implementation.



Consumer engagement

The VCCC and its Cancer Consumer Advisory Committee (CCAC) are committed to embedding consumer engagement into all aspects of the VCCC cancer program, which is also in-line with international best practice and complies with the Department of Health Standard 2, Partnering with Consumers. In 2016 the VCCC established the Cancer Consumer Advisory Committee (CCAC) to review and oversee:

The purpose of the Committee is to assist the Board to review and oversee:

- The development of consumer engagement projects which could include the development of a patient-to-patient support program or training programs for both health professionals and consumers.
- Any VCCC projects that would reasonably benefit from consumer input.
- Harmonisation and support of existing consumer programs in partner organisations.

Guided by the 'National Framework for Consumer Involvement in Cancer Control' published by Cancer Australia and Cancer Voices Australia, the VCCC is developing a comprehensive and integrated consumer engagement framework that facilitates embedding consumer engagement in all VCCC activities, and particularly in the 19 programs of work described in the VCCC Strategic Research Plan. The consumer engagement framework will:

- be tailored to the VCCC's organisational context and its role in the translation of new research and evidence into routine care for cancer patients
- provide a clear methodology for implementation including timelines and resources required for implementation
- include the evidence-base and rationale for how the framework and the methodology for implementation were developed
- include an evidence-based evaluation framework and program logic to enable assessment of the impact of consumer engagement on both programs of work and on the VCCC organisation as a whole
- be constructed to facilitate evolution of the framework as the VCCC evolves over time

As the framework is under development, CCAC has proposed priorities for the level of consumer involvement in each SRP program to provide a basis for integrating consumer involvement into the VCCC. These recommendations were based on the levels of consumer engagement (Inform, Consult, Involve, Collaborate, Empower) as outlined in the Cancer Australia National Framework for Consumer Involvement in Cancer Control. This is outlined in Appendix C.

Implementation

Initiatives in the SRP will be delivered by the VCCC in partnership with its member organisations, with substantial outreach across the Victorian health system. The VCCC will provide co-ordination where required.

The VCCC has established a project management framework to support good project management and governance, while empowering program teams to come up with creative and innovative ways to implement the co-designed programs to support the goals of the program and broader strategic objectives and principles of the VCCC. It recognises that while some structure is necessary to ensure delivery and accountability of work, agility to respond to innovation is important without feeling constrained by overly rigid processes.

The primary aim of utilising a project management framework is to ensure that projects remain on track, have the necessary approvals at each stage, and to ensure stakeholders are fully engaged and informed

on project progress. Part of the project management framework includes development of a Project Plan to guide the program development. The Project Plan template covers the following areas:

- Background and rationale
- Scope
- Methodology
- Deliverables
- Timelines
- Project team and governance
- Measures of success
- Ethics, data safety and monitoring (if relevant)
- Measures of success
- Budget
- Risk management
- Tolerances and exceptions
- Reporting requirements
- Communications plan
- Sustainability

Throughout the program scoping phase, consideration has been given to such factors as potential leverage opportunities, other funding sources and sustainability.

Corrective Action Process

Once developed, the Project Plan will outline the agreed scope and direction of that program. During program implementation, a key risk is scope creep. A corrective action process has been established to ensure that there is accountability and an appropriate decision-making process for any variation, along with the governance and record-keeping arrangements in place to respond to situations that may be considered problematic for the program or the organisation.

The VCCC Project Management Framework has set tolerances for cost, time and scope and utilises a risk framework to identify any risks and set the mitigating strategies.

At a program level, if a problem or risk is identified, this is initially considered by the program team before being raised with the Steering Group for consideration. If the problem or risk is unable to be mitigated, this feeds through the SRP Governance Framework for the appropriate decision-making process. If a significant change in program scope, budget or timeline is identified, this will be raised with the DHHS for consideration. Any variation requests will utilise the DHHS Variation Request Form to seek a decision.

At a broader level, the Cancer Research Advisory Committee (CRAC) will provide ultimate oversight of the Strategic Research Plan and will review programs and overall strategy on a regular basis to ensure the direction remains appropriate.

Key tools to manage the corrective action process include:

- VCCC Project Management Framework
- VCCC Project Plan
- VCCC Program Tolerances
- VCCC Governance Framework & Delegated Authority
- VCCC Program Reporting Framework
- VCCC Risk Management Framework
- VCCC Variation and Decision log
- VCCC Exception Report
- DHHS Variation Request Form

Variation and responsiveness to emerging and innovative ideas

The VCCC is operating in a constantly evolving and changing landscape. During the implementation of the Strategic Research Plan programs in the 2017-2020 funding agreement period, we anticipate that

there will be new or emerging areas that merit VCCC investment, and other areas that will require less funding. Building some agility into the SRP has been identified as an important way to mitigate the risk of not responding to new or rapidly advancing areas of cancer research.

The VCCC will monitor program budgets and, if through leverage opportunities or reduced expenditure in underperforming areas, currently untied funds are identified, the VCCC will prioritise investment in areas of existing programs where success has been demonstrated or where further expansion will produce greater benefits, or cutting-edge areas that align with VCCC strategy and principles. Such decisions will follow the SRP governance process. Any new idea or opportunity that aligns with the SRP principles will be considered by the Cancer Research Advisory Committee, a recommendation made to the VCCC Board and then put forward to DHHS for consideration and a variation.

The total committed program funding at the date of the Strategic Research Plan submission amounts to around $29.7m. An initial pool of around $300,000 will be available to draw upon to support any emerging and innovative areas of potential work.

For example, expansion of the Building Trial Group Capability program into new trial groups (such as supportive care, surgical oncology, allied health and/or other groups) could be such a consideration upon successful implementation of the palliative care trial group.

Communication

Because of the size and scope of the 19 programs, the VCCC will further build communications capacity to ensure all VCCC partners, the sector, and the community are aware of our programs of work and the ways in which they can contribute or participate. A communications strategy is being developed which will include:

- Production of a public facing version of the Strategic Research Plan.
- Dissemination of the Strategic Research Plan to key stakeholders to communicate the strategic direction for the funding.
- Promotion of program activities and opportunities for engagement and collaboration.
- Communication of program benefits and outcomes to key stakeholders.

Leverage and sustainability

A principle used for the prioritisation and planning phases of developing the SRP has been the identification of where the VCCC can add value to work currently being undertaken. The VCCC model of fostering strong partnerships is central to all aspects of the SRP and these partnerships will assist in sustaining the most successful ongoing endeavours. Other avenues through which new research activities may have the opportunity to be sustained include:

- attracting new funding from NHMRC and MRFF
- attracting philanthropic funding
- generating additional industry-funded clinical trials and associated research
- generating new partnerships with industry

Translation of research findings into routine care will sustain the longer-term benefits of the most successful research.

Each program is identifying and testing mechanisms for sustainability. Initial possibilities for leverage and sustainability have been identified within each program.

Measures of success

An evaluation framework, including program logic and measures of success, are being established for activities within each program. Program-level evaluations will underpin assessment of the net outcomes of this strategic research plan. Learnings from evaluation will provide the evidence-base to guide the direction of VCCC work beyond 2020.

Data Safety and Monitoring for Clinical Trials

Data safety and monitoring is the responsibility of each VCCC partner under mandate of NHMRC certified HRECs that report to the hospital executive and Board

All Alliance partners have confirmed they conduct clinical research within the regulatory framework defined by the International Council for Harmonisation Guideline for Good Clinical Practice (ICH GCP E6), NHMRC guidance documents including the Australian Code for the Responsible Conduct of Research, The National Statement on Ethical Conduct in Human Research, Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods as well as the regulatory requirements of the Therapeutics Goods Administration.

Routine monitoring of clinical trial conduct at individual sites is performed by external bodies such as Sponsors, Clinical Research Organisations and Cooperative trial groups. Clinical trial site audits are also conducted by the same external bodies but also include formal audits by the FDA or random audits by Site Research Directorates.

Standard Operating Procedures (SOPs) defining how clinical research is conducted are maintained by the clinical research groups within the Hospitals and follow hospital policies while taking guidance from VMIA. In additional, Sites routinely assess internal performance of their trial portfolio, individual trials and other key performance indicators according to their own SOPs using internally and externally derived metrics.

Education and Training Strategy

Pivotal to the success of the programs outlined in the Strategic Research Plan is the development of the cancer workforce in Victoria. Integrated into each program of work are the relevant education and training activities. Key areas include the development of a Masters of Cancer Sciences, an educational program for development of the clinical trials workforce and nursing research workforce. The VCCC Education and Training Strategy is included at Appendix D.

SRP Contract Milestones

Engage and consult with VCCC members and the VCCC Cancer Research Advisory Committee to develop the Strategic Research Plan - Initial consultative forum - Final consultative forum	November 2016 and ongoing - November 2016 - April 2017
Establish Terms of Reference with DHHS	December 2016/January 2017
Submission of Progress Report	April 2017
Draft Strategic Research Plan VCCC Board endorsement of Draft Strategic Research Plan under the pre-existing VCCC Joint Venture agreement and constitution. Commencement of work that tests and validates the implementation of key priority programs.	June 2017
Development of Project Management Framework to support SRP program delivery	June 2017
Appointment of Program Managers for SRP Programs	July 2017
Detailed program planning	July 2017 and ongoing
Establishment of SRP Governance Structure	August 2017
Final Strategic Research Plan Submission following VCCC Board endorsement	October 2017
Submission of VCCC Annual Report	October 2017
Submission of Progress Report	April 2018
Report against Comprehensive Cancer Centre Research ranking (international impact ranking, 5-year measure) for 2011-2015 calendar years	30 September 2018
Report against annual clinical trial activity for the following calendar years: - 2016 and 2017 - 2018 and 2019	 30 September 2018 30 September 2020
Report against annual cancer research income to Member Entities for the following financial years: - 2014/15 to 2015/16 - 2016/17 to 2017/18	 30 September 2018 30 September 2020
Submission of VCCC Annual Report	October 2018
External independent review of the VCCC's activities, including the Strategic Research Plan	Feb – June 2019
Submission of Progress Report	April 2019
Submission of VCCC Annual Report	October 2019
Submission of Progress Report	April 2020
Final report detailing achievements and outcomes	October 2020

Appendices

Appendix A: Methodology and acknowledgements

Appendix B: Principles for prioritisation of proposed SRP programs

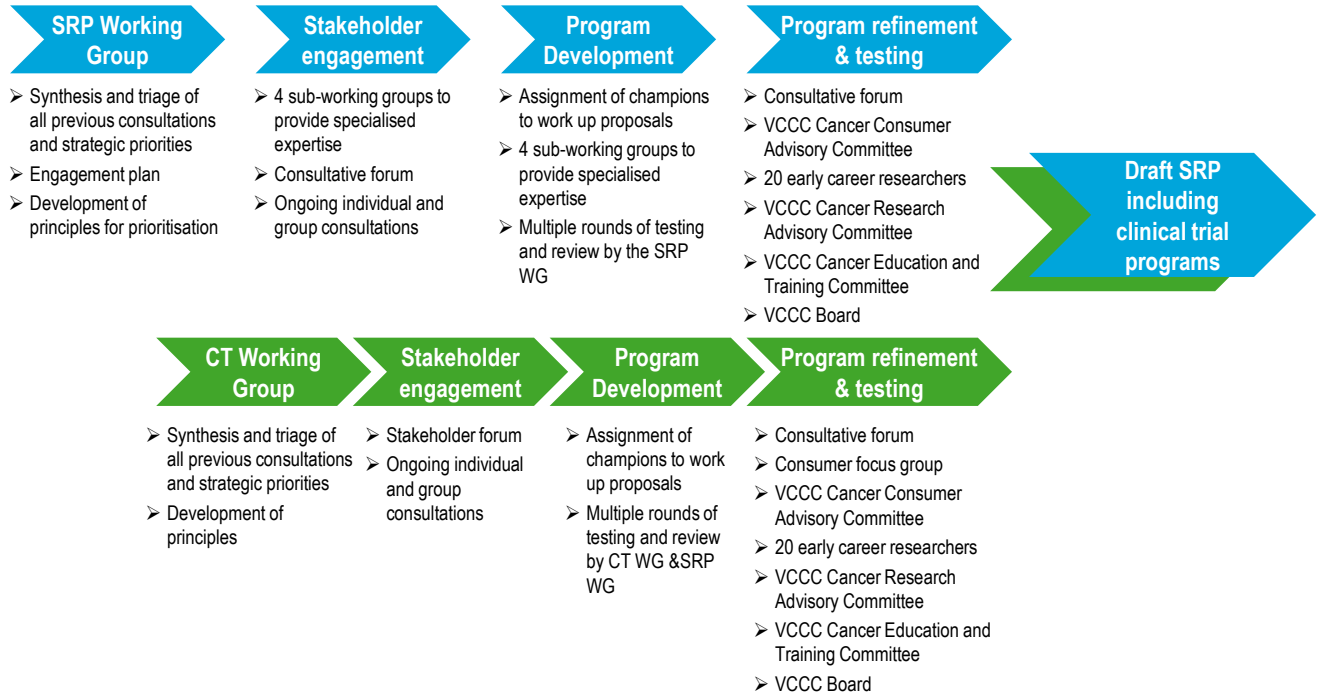
Appendix C: Summary of the Strategic Research Plan

1. Connectivity between programs and noting connections and synergies with cancer-related organisations external to the VCCC alliance
2. Consumer engagement
3. VCCC alliance partner involvement
4. Program contribution to clinical trials participation rates along with anticipated outcomes

Appendix D: Education and Training Strategy

Appendix A: Methodology and acknowledgements

The first steps for development of this Strategic Research Plan were to consolidate the extensive consultation undertaken by the VCCC since 2009, and to develop an engagement plan to guide further consultation with key stakeholders.



A Strategic Research Plan Working Group (SRP WG) that represented VCCC partners and a breadth of expertise in cancer research, education and care was formed. The SRP WG's role was to create and deliver a transparent and appropriate process for identification, prioritisation and selection of programs of work for inclusion in the Strategic Research Plan.

After consideration of all feedback and consultation conducted by the VCCC over more than 5 years including at a Consultative Forum in November 2016, the SRP WG identified a number of areas of unmet need which could be addressed by VCCC programs of work.

The SRP WG developed a set of principles (Appendix B) against which to prioritise all of the potential programs of work identified to date, then systematically worked through all of the potential programs of work, assessed them against the principles, and prioritised them for inclusion in the SRP.

Champions were identified for each potential program, which were then further co-developed with the SRP WG and the VCCC, then refined and tested. Greater expertise was provided where required by sub-working groups of the SRP WG, including ones for clinical trials, data, targeted therapies and immunotherapy, as well as by the VCCC Cancer Education and Training Committee (CETAC). To date, the prioritised programs have been tested at a consultative forum in April 2017 which was attended by consumer representatives, the Department of Health and Human Services and VCCC members, as well as by the VCCC Cancer Research Advisory Committee and through solicited feedback from early career researchers from across the VCCC alliance. The clinical trial component of the SRP has been further tested at a consumer focus group.

The VCCC is grateful to the many researchers, health care professionals and educators (listed below) who contributed to the co-development of the Strategic Research Plan.

Strategic Research Plan Working Group

Name	Current VCCC Role	Organisational Role(s) for Partners
Andrew Roberts	Chair of CRAC VCCC Research and Education Lead for Haematology Leaders in Cancer Program: Metcalf Chair of Leukaemia Research	**WEHI**: Head of Clinical Translation, Cancer and Haematology Division **MH**: Clinical haematologist **UoM**: Metcalf Chair of Leukaemia Research
Grant McArthur	VCCC Executive Director Expert Member on CRAC VCCC Research and Education Lead for Melanoma and Skin Cancers Leaders in Cancer Program: Lorenzo Galli Chair in Melanoma and Skin Cancers	**Peter Mac**: Program Head, Cancer Therapeutics & Oncogenic Signalling & Growth Control Programs, Tumour Stream Director, Melanoma & Skin **UoM**: Lorenzo Galli Chair in Melanoma and Skin Cancers
Jon Emery	Expert Member on CRAC VCCC Research and Education Lead for Primary Care Leaders in Cancer Program: Herman Chair of Primary Care Cancer Research	**UoM**: Herman Chair of Primary Care Cancer Research **WH**: Herman Chair of Primary Care Cancer Research
Mei Krishnasamy	Member of CETAC Leaders in Cancer Program: Chair in Cancer Nursing VCCC Research and Education Lead for Cancer Nursing	**UoM**: Chair in Cancer Nursing, Department of Nursing, School of Health Sciences
Gavin Wright	VCCC Research and Education Lead for Lung Cancer	**SVHM**: Director of Surgical Oncology **Peter Mac**: Thoracic Surgeon
Peter Gibbs	VCCC Research and Education Lead for Gastro-intestinal Cancers	**WH**: Medical Oncologist **WEHI**: Laboratory Head, Systems Biology and Personalised Medicine Division
Mark Rosenthal	VCCC Clinical Trial Development Lead	**Peter Mac/MH**: Director, Parkville Cancer Clinical Trials Unit
Sean Grimmond	Expert Member on CRAC	**UoM**: Director & The Bertalli Chair in Cancer Medicine, UoM Centre for Cancer Research
Ricky Johnstone	Chair, VCCC Research Conference Organising Committee	**Peter Mac**: Assistant Director, Cancer Research, Co-head, Cancer Therapeutics Program, Group Leader, Cancer Immunology Program & Translational Haematology Program
Jenny Philip	Leaders in Cancer Program: Chair of Palliative Medicine	**SVHM**: Senior clinician **UoM:** Chair of Palliative Medicine
Andrew Scott		**AH/ONJCRI**: Head, Tumour Targeting Laboratory, Scientific Director of Positron Emission Tomography. **CTA:** Board Chair
Orla McNally		**RWH**: Director of Oncology and Dysplasia and Director, Gynaeoncology Service

Key to abbreviations

VCCC	*Victorian Comprehensive Cancer Centre*	*RMH*	*Royal Melbourne Hospital*
AH	*Austin Health*	*RWH*	*Royal Women's Hospital*
MH	*Melbourne Health*	*SVHM*	*St Vincent's Hospital Melbourne*
ONJCRI	*Olivia Newton John Cancer Research Institute*	*UoM*	*University of Melbourne*
Peter Mac	*Peter MacCallum Cancer Centre*	*WEHI*	*Walter and Eliza Hall Institute of Medical Research*
RCH	*Royal Children's Hospital*	*WH*	*Western Health*
CRAC	*Cancer Research Advisory Committee*	*CETAC*	*Cancer Education & Training Advisory Committee*
CCAC	*Cancer Consumer Advisory Committee*		

The Strategic Research Plan Working Group was supported by a number of sub-working groups whose Chairs are listed below and whose members are listed at the end of this appendix along with members of the VCCC's Cancer Research Advisory Committee, Cancer Education & Training Advisory Committee and Cancer Consumer Advisory Committee who have contributed to the development of the VCCC Strategic Research Plan.

Chairs of all sub-working groups are members of the Strategic Research Plan Working Group.

Working Group	Chair
Clinical Trial Development Working Group	Mark Rosenthal
Immunotherapy Working Group	Grant McArthur
Data Working Group	Jon Emery
Response & Resistance to Targeted Therapies Working Group	Andrew Scott & Andrew Roberts

Contributors through Working Groups and Advisory Committees

Alex Boussioutas	RMH, Peter Mac, UoM	Katy Weare	RWH
Allison Lamb	RCH, MCRI	Katya Gray	CCAC
Bernadette O'Connor	RCH	Keith Donahoe	CCAC
Bruce Mann	RWH, RMH, Peter Mac	Les Leckie	CCAC
Caroline Owen	Peter Mac	Lorey Smith	Peter Mac
Carolyn Rowan	CCAC	Margaret Kelaher	UoM
Clare Scott	WEHI, RMH, Peter Mac	Marian Lieschke	Peter Mac
Dale Godfrey	UoM	Mark Dawson	Peter Mac
Dallas English	UoM	Mark Jenkins	UoM
David Ritchie	RMH, Peter Mac	Matthias Ernst	AH/ONJCRI
David Smallwood	RMH	Maureen Turner	BioGrid Australia
Dish Herath	WH, RMH, Peter Mac	Megan Chiswell	Cancer Council Victoria
Dougie Boyle	UoM	Michael Green	WH
Judith Slocombe	CCAC	Michael Henderson	Peter Mac
Edward Janus	WH, UoM	Nick Huntington	WEHI
Fabienne Mackay	UoM	Nick Nicola	WEHI
Francoise Mechinaud	RCH	Paul Baden	CCAC

Geoff McColl	UoM
Heather Beanland	CCAC
Hui Gan	AH/ONJCRI
Ingrid Winship	RMH
Jayesh Desai	Peter Mac, RMH, WEHI
Jo Cockwill	CCAC
Joe Trapani	Peter Mac
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Paul Ekert	MCRI
Richard Khor	AH
Sandra Nicholson	WEHI
Sheila Kanji Patel	CCAC
Sherene Loi	Peter Mac
Sophy Athan	CCAC
Stephen Lew	WH
Sue-Anne McLachlan	SVHM
Tony Burgess	WEHI
Wilma Beswick	SVHM

Appendix B: Principles for prioritisation of proposed SRP programs

The VCCC Strategic Research Plan Working Group and the VCCC Cancer Research Advisory Committee agreed a set of principles for prioritisation of potential programs of work based on DHHS requirements and VCCC Board directions.

These principles are:

- Must address an unmet need
- Must have the opportunity to proceed with respect to:
    - the local environment
    - the international environment/activity/competition
    - current funding/activity that could be leveraged
    - opportunity for significant growth through VCCC investment
- Consumers must be engaged/ involved in the program at the appropriate level
- Programs should be able to leverage and/or self-sustain
- The quality of the program and outputs should be internationally competitive and aspire to be best in Australia
- Programs should have elements assessable for short, medium and longer term outcomes
- Programs could provide broader community benefit if applied within other areas of the VCCC and/or outside the VCCC
- Programs should involve and benefit multiple VCCC partner organisations, with higher priority for programs that are across all/most of the VCCC or that establish robust new linkages / activities
- Programs should build capacity, which may be people, technology or workforce (through education or mentorship)

The Clinical Trial Working Group added some further criteria for prioritisation of programs within the clinical trial component of the Strategic Research Plan:

- Programs should provide resources to sites rather than centralise
- Programs should enable cross-appointments and movement of staff around VCCC partners to facilitate collaboration
- Programs should reflect in preferential order what is in the best interests of all Victorians, then in the interests of VCCC patients, and then in the interests of individual sites
- Programs should focus on investigator-initiated trials in particular and co-operative group trials
- Programs should be applicable to non-VCCC sites
- Programs should complement the work of other organisations acting to improve the clinical trial landscape

Appendix C: Summary of the Strategic Research Plan

1. Connectivity between programs and noting connections and synergies with cancer-related organisations external to the VCCC alliance

Program	Interface with clinical trial activity	Capability and capacity building	Translation into practice	Developing the workforce	Connections and synergies with other platforms in the cancer field that will be explored
Immunotherapy	+	++	+	+	Cell Therapies, Parker Institute for Cancer Immunotherapy, industry
Precision Oncology	+	+	++	+	Melbourne Genomics Health Alliance, Cancer 2015, ICGC, TCGA
Precision Prevention and Tailored Screening	+	+	+	+	Cancer Council Victoria, BreastScreen, CRE in optimising CRC screening
Understanding Response and Resistance to Targeted Therapies	++	++	+	+	Melbourne Genomics Health Alliance, Victorian Cancer Biobank, ACRF Translational Proteomic Facility, ACRF Centre for Translational Research and Imaging, Cart-Wheel, Melbourne Melanoma project, Cancer 2015, industry
Research and Education Lead program	+	++	++	++	
Building Analytical Capability for Data-driven Research		++	+		BioGrid, Victorian Cancer Registry
Building Nursing Research Capability		+	+	++	CNSA, COSA, ACU
Building Connectivity	+	++	++	++	BioMedVic
Master of Cancer Sciences				++	CRC for Cancer Therapeutics, CCV
	Theme				
Development of Workforce Capacity and Capability	Workforce Development			++	BioMedVic, CRC for Cancer Therapeutics, MACH
Investigator-initiated Trial Capacity Building	Capacity building	++	+		Cancer Trials Australia, MPCCC, MACH
Building Capacity through Efficiency		++			Cancer Trials Australia, MACH
Building Trial Group Capability	Expanding the trial portfolio	++	+	++	
New Approaches to Clinical Trials		++	+		Melbourne Genomics Health Alliance, MPCCC
Registry Trials		++	+		BioGrid, Melbourne Melanoma Project, MPCCC
Teletrials	Increasing Access	++			MPCCC,Cancer Trials Australia, regional cancer centres, industry
Increasing Awareness of Clinical Trials		++			Melbourne Genomics Health Alliance, Cancer Trials Australia, Cancer Council Victoria, industry, nations clinical trial co-operative groups
Increasing AYA Clinical Trial Access		++			MACH, MPCCC
Metrics for Clinical Trial Participation	Measurement and impact	++	+	+	Cancer Trials Australia, Cancer Council Victoria, MPCCC

2. Strategic Research Plan Consumer Engagement

Proposed priorities for consumer engagement in Strategic Research Plan Programs

	Proposed level of consumer engagement				
Programs	**Inform**	**Consult**	**Involve**	**Collaborate**	**Empower**
Immunotherapy		✓	✓		
Precision Oncology				✓	✓
Precision Prevention and Tailored Screening		✓	✓		
Understanding Response and Resistance to Targeted Therapies	✓	✓			
Investigator-initiated Trial Capacity Building				✓	✓
Building Capacity through Efficiency	✓				
Building Trial Group Capability		✓	✓		
New Approaches to Clinical Trials	✓				
Registry Trials		✓	✓		
Teletrials		✓	✓		
Increasing Awareness of Clinical Trials			✓	✓	
Increasing AYA Clinical Trial Access	✓	✓			
Development of Workforce Capacity and Capability		✓	✓		
Metrics for Clinical Trial Participation				✓	✓
Research and Education Lead program			✓	✓	
Building Analytical Capability for Data-driven Research				✓	✓
Building Nursing Research Capability			✓	✓	
Building Connectivity		✓	✓		
Master of Cancer Sciences	✓	✓			

3. Strategic Research Plan VCCC Partner Involvement

Proposed areas of engagement and activity across VCCC alliance partners in the delivery of the Strategic Research Plan Programs

Program	AH	RMH	PMCC	RCH	RWH	SVHM	WH	MCRI	WEHI	UoM
Immunotherapy	++	++	+++	+	+	+	+	+	++	+++
Precision Oncology	+	+	++	++	+	+	+	++	+	++
Precision Prevention and Tailored Screening		+			+		+		+	++
Understanding Response and Resistance to Targeted Therapies	++	+	++	+	+	+	+		++	
Research and Education Lead program	++	++	++	++	++	++	++	+	+	++
Building Analytical Capability for Data-driven Research	+	+	+	+	+	+	+	+		++
Building Nursing Research Capability	+	+	+	+	+	+	+			++
Building Connectivity	+	+	+	+	+	+	+	+	+	+
Master of Cancer Sciences	+	+	+	+	+	+	+	+	+	++
Development of Workforce Capacity and Capability	+	+	+	+	+	+	+			
Investigator-initiated Trial Capacity Building	+	+	+	+	+	+	+	+		+
Building Capacity through Efficiency	+	+	+	+	+	+	+			
Building Trial Group Capability	+	+	+	+	+	+	+			
New Approaches to Clinical Trials	+	+	+	+	+	+	+			
Registry Trials	+	+	+	+	+	+	+	+	+	+
Teletrials	+	+	+	+	+	+	+			
Increasing Awareness of Clinical Trials	+	+	+	+	+	+	+			
Increasing AYA Clinical Trial Access	+	+	+	++	+	+	+			
Metrics for Clinical Trial Participation										

4. Program contribution to clinical trials participation rates along with anticipated outcomes

Programs	How programs should enhance clinical trial participation											How proposed programs contribute							Net Effect
	Barriers to be removed					Enablers to be introduced						Anticipated Outcomes							
	Inadequate infrastructure for investigator-initiated trials	Inadequate infrastructure for co-operative group trials	Insufficient cohesion in tumour streams	Insufficient genomic matching	Access for rural/ regional patients	Support for new investigators	Increased trial workforce	Upskilled workforce	Augmenting specialised investigation capacity	Streamlined governance and processes	Tools to identify appropriate trials	Additional commercial investment / trials	Additional non-commercial funding for trials	Easier to do trials	Greater workforce & infrastructure to run trials	Expand the range of clinical trials undertaken	More patients eligible for trials	More clinical trials initiated	More clinical trial participants
Investigator-initiated Trial Capacity Building	+ +	+	+			+ +	+	+					+		+		+	+ +	+++
Building Capacity through Efficiency		+								+		+		+				+	+
Building Trial Group Capability		+				+	+					+ +	+		+	+	+	+	+ +
New Approaches to Clinical Trials				+		+						+	+		+	+	+	+	+
Registry Trials						+	+	+		+		+	+	+	+	+	+	+	+ +
Teletrials					+			+		+		+		+	+		+		+
Increasing Awareness of Clinical Trials						+					+			+					+
Increasing AYA Clinical Trial Access										+				+			+		+
Development of Workforce Capacity and Capability							+	+							+			+	+
Metrics for Clinical Trial Participation												+							+
Immunotherapy								+	+			+	+		+		+	+	+
Precision Oncology				+				+	+				+				+	+	+
Precision Prevention and Tailored Screening*													+			+			(+)
Understanding Response and Resistance to Targeted Therapies									+			+	+		+		+	+	+
Research and Education Lead program			+									+						+	+
Building Analytical Capability for Data-driven Research																		+	
Building Nursing Research Capability						+	+	+					+		+	+	+		+
Building Connectivity		+				+						+							+
Master of Cancer Sciences								+	+						+				

Legend:

Intensity of red red colour represents the cumulative positive effect on cancer clinical trial participation

Lighter orange indicated contributions from non-clinical trial programs

* Most of those participating in prevention or screening trials will not have cancer, thus this program will contribute to increased numbers of cancer clinical trials rather than increased clinical trial participation by cancer patients

Appendix D: VCCC Education and Training Framework

Preamble

Founded in the holistic principles of the internationally recognised Comprehensive Cancer Centre model, the Victorian Comprehensive Cancer Centre is a unique and powerful alliance of 10 leading research and clinical institutions committed to working together to integrate and accelerate cancer research, treatments, preventions and care. The VCCC's multi-site, multi-disciplinary model brings together the complementary strengths and specialisations of Peter MacCallum Cancer Centre, Melbourne Health (including The Royal Melbourne Hospital), The University of Melbourne, The Walter and Eliza Hall Institute of Medical Research, The Royal Women's Hospital, The Royal Children's Hospital, Western Health, St Vincent's Hospital Melbourne (including St Vincent's Institute), Austin Health (including the Olivia Newton-John Cancer Research Institute and Austin Lifesciences) and Murdoch Children's Research Institute.

The VCCC aims to bolster the global competitiveness of these member organisations by creating a critical mass that can overcome the problems of scale and geography to attract optimal research funding, the best researchers, clinicians and teachers and industry support including international clinical trials. Based on the world-class model for excellence of comprehensive cancer centres in the United States, the VCCC strives to reduce the burden of cancer in our community by creating an international centre of research, clinical care and teaching excellence by enabling deeply embedded collaboration and joint programs.

Context

The VCCC has completed its initial Funding Agreement (2009-2016) and has signed a new four-year Funding Agreement (2016-2020) with the Victorian State Government. This agreement includes a number of expectations from the Department of Health and Human Services (DHHS) for ongoing work for the VCCC as a translational research platform in cancer. It also provides an opportunity to refresh the VCCC program and to consider new and innovative ideas for the next phase of the VCCC. With the VCCC building project now complete and the new funding agreement in place, the VCCC is well positioned to consolidate achievements to date and establish a clear framework for current and future work. This will be articulated in a VCCC Strategic Research Plan that must be submitted to the Victorian State Government by October 2017.

Strategic Research Plan

Strategic Objectives

The VCCC Strategic Research Plan will focus on four broad areas:

1. Building research capability
2. Translating research into practice and policy
3. Developing the cancer clinical trials program
4. A framework for cancer education and training

Through innovation and collaboration, the VCCC will develop an education and training framework that will support workforce development in the broad areas of focus for the Strategic Research Plan.

Identified education and training needs

The VCCC cancer workforce consists broadly of two groups: (1) the research workforce which consists of researchers and research trainees from multiple disciplines with backgrounds in laboratory research, population health or clinical research; and multidisciplinary clinicians who hold clinician-researcher or

clinician-scientist positions and (2) the clinical workforce that includes professionals involved in delivering patient care including, the medical, nursing, allied health and radiation therapy sectors.

Since 2011 there have been various approaches used to determine the education and training needs of the VCCC cancer health workforce. These have included the following pieces of work:

1. Needs analysis: Activity and Capability census (2011)
2. Needs analysis: Research Higher Degree Study into research training experience (2012-2013)
3. Census of Leadership Development (2013)
4. Environmental scan of Research and Education Leads program (2016)
5. Strategic Research Forum evaluation results (2016)

Strategy

The end of 2016 represents an important transition point for the VCCC Cancer Education and Training Committee (CETAC). With the commissioning of the VCCC building complete it is now time to reconsider the education and training strategy and program in light of achievements over the past 5 years and opportunities in the future. This brief document outlines such a strategy.

Mission

The VCCC Education and Training Strategy positions our cancer workforce to embrace and develop evidence and technologies to fully address the grand challenges faced by people affected by cancer and those presented by this group of diseases. The VCCC will become the national hub for education and training in cancer research and care.

Principles underlying the strategy

- Education and training is embedded into the clinical and research activities of the partners
- Modern and effective educational methods are utilised for all educational and training activities
- VCCC partners co-operate to enhance education and training programs where appropriate
- VCCC education and training programs are accessible to cancer researchers and clinicians across Victoria beyond the alliance partners
- Efficient, engaging and effective education and training underpins translation of new research evidence into routine clinical practice
- Education is valued at the same level as research and clinical care.

Theme 1 Clinical and Research Training			
Objective	**Strategy**	**Actions**	**Education and Training Program**
• The VCCC will become the preeminent national and regional centre of excellence for training the multidisciplinary cancer clinical, research and education workforce of the future.	• Integrate the training needs of doctors, nurses, allied health professionals and researchers in the broader Education and Training framework	• Apply the education and training framework to develop an optimally skilled and knowledgeable workforce in collaboration with the colleges and universities	• VCCC Education and Training Strategy and Framework • All programming
	• Provide a stratified training program accordingly to stages of career, scope of practice, competency requirements e.g. Specialist Certificate, Grad Cert and Master's program, PhD program, specialist training programs, higher degree students, post-doctoral training, medical fellowship programs, preceptorship programs etc.	• Apply the education and training framework to develop an optimally skilled and knowledgeable workforce in collaboration with the colleges and universities • Develop and deliver the Masters of Cancer Sciences nested program • Support the development and delivery of the CCC PhD program and Fellowship and preceptorship programs • Provide complementary programming to standardise training in particular procedures and skills	• Specialist Certificate, Graduate Certificate and Masters of Cancer Science • Fellowship programs for cancer nursing researchers and clinical trials workforce • Comprehensive Cancer Centre PhD program • Post doctoral symposium
	• Build a community of practice that can enable supervisors and trainers to better support trainees, students and each other	• Develop faculty through supporting their participation in higher degrees, train the trainer and educator mentoring programs • Create a community of practice and mentoring for educators across the partners • Develop a reward and recognition program for VCCC educators	• Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Communities of Practice including Mentoring program and Special Interest Groups • Educator Reward and recognition program
	• Support the VCCC partners to develop training programs that align with the learned colleges	• Develop faculty through supporting their participation in higher degrees, train the trainer and educator mentoring programs	• Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Primary Care Weekend Education Series
Theme 2 Continuing professional development			
Objective	**Strategy**	**Actions**	**Education and Training Program**
• The VCCC supports its multidisciplinary cancer clinicians and researchers through provision of an outstanding professional development program to	• Identify high priority learning and education needs that could be supported efficiently by harmonising the activities of partners	• Identify the professional development needs of the cancer workforce at each of the ten partner organisations • Integrate the professional development needs of doctors, nurses, allied health professionals	• Consolidated needs analysis • VCCC Education and Training Strategy and Framework • Strategic Research Plan process

keep the workforce at the cutting edge of new development		and researchers into the broader VCCC Education and Training Framework	
	• Audit existing professional development programming and identify opportunities for collaboration, consolidation and co-ordination	• Map pre-existing professional development programming and identify gaps or areas of enhancement aligned to VCCC strategic goals and priorities	• Audit of professional development programming around the partners • VCCC Education and Training Strategy • VCCC Education and Training Framework • Strategic Research Plan process
	• Foster a cancer care workforce of lifelong learners	• Develop new innovative cancer-related professional development programs with a focus on inter-professional education in research and clinical care • Develop a consistent approach to mentoring and peer review	• All programming • Picchi Awards for Cancer Research • Educator Reward and Recognition program • Communities of Practice including Mentoring program and Special Interest Groups • Online education programming for tumour and cross cutting streams • Workforce capacity and capability for clinical trials • Novel trial design • New trial groups • Immunotherapy • Understanding resistance to targeted therapies • Precision Oncology • Precision Prevention • Building nursing research capability for better patient outcomes • Scholarship programming • VCCC Communications strategy • Learning Management System
	• Evaluate and continually improve VCCC professional development programs	• Integrate the professional development needs of doctors, nurses, allied health professionals and researchers into the broader Education and Training framework	• Evaluation plan of the VCCC Education and Training Framework • Individual program evaluation reports
Theme 3 Patient education and awareness			
Objective	**Strategy**	**Actions**	**Education and Training Program**
All patients treated at a VCCC organisation can access evidence based educational materials and programming	• Work with the partner organisations to add value to their programs by addressing patient and carer reported needs based education and awareness	• Identify the gaps or areas for enhancement in patient education and if the VCCC could best address this gap • Co-develop educational patient materials and programming where appropriate leveraging off the strengths within the partnership • Work with affiliated organisations such as Cancer Council Victoria (CCV) to enhance patient information and programming	• Inaugural Research conference • Survivorship conference • Psycho oncology conference • VCCC Consumer Advisory Committee

	• Enhance awareness of patient education and information provided by the partner organisations	• Integrate available patient information and programming into relevant educational programming for clinicians	• VCCC Education and Training Framework • Specialist Certificate, Graduate Certificate and Masters of Cancer Science • All clinical programming • All future programming • Website • Social media platforms • Learning management system • VCCC Consumer Advisory Committee
	• Support clinicians on how to access patient information and education and screen for patient information needs	• Integrate available patient information and programming into relevant educational programming for clinicians	• VCCC Education and Training Framework • Specialist Certificate, Graduate Certificate and Masters of Cancer Science • All clinical programming • All future programming • Website • Social media platforms • Learning management system • VCCC Consumer Advisory Committee
Theme4 connections and partnerships			
Objective	**Strategy**	**Actions**	**Education and Training Program**
• Connect likeminded educators to come together around key multisite educator programs and resources	• Establish an engagement plan and working groups that enable the efficient and effective coordination of education and training programs	• Develop a collaboration and engagement framework for VCCC associated educational activities	• VCCC Communications strategy • Learning Management System • Website • Social media platforms
	• Develop an inter-professional and inter-institutional faculty group to develop and deliver educational projects	• Create working parties under the Cancer Education and Training Advisory Committee to develop educational programming • Support faculty development through train the trainer and other programs • Create a community of practice and mentoring for educators across the partners	• Communities of Practice including Mentoring program and Special Interest Groups • Educator Reward and recognition program • Learning Management System • CETAC terms of reference and organisational structure • Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators
	• Create opportunities for interaction, between members of the partner organisations and different craft groups (particularly researchers and clinicians)	• Include networking opportunities around educational programming where appropriate • Create communities of practice for cancer nursing educators, medical educators, research educators etc. in order to increase collaborative partnerships, quality and efficiency	• Communities of Practice including Mentoring program and Special Interest Groups • Learning Management System • All current programming • All future programming
	• Extend the reach of the education and training programming to incorporate	• Incorporate online modalities into all programming as appropriate	• Survivorship training for primary care practitioners • Learning Management System

	primary care and regional cancer workforces		• Research and Education Leads program and online education program • All current and future programming delivered by the VCCC will be reflected on the LMS and house recordings and resources of the program for others to view • Chair, Regional Oncology
	• Support leaders and provide opportunities which promote the co-operative management and development of shared education and training resources	• Develop a collaboration and engagement framework for VCCC associated educational activities	• VCCC Education and Training Strategy and Framework • Strategic Research Plan process • VCCC Leadership program • Research Development and Leadership Program • Specialist Certificate in Clinical Leadership • Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Learning Management System
	• Build on existing collaborations and facilitate expansion of existing collaborations to other partners	Develop a collaboration and engagement framework for VCCC associated educational activities	• Strategic Research Plan process • Special interest groups
Theme 5 Organisational systems			
Objective	**Strategy**	**Actions**	**Education and Training Program**
• VCCC education and training programs are underpinned by best practice tools, resources and platforms	• Use innovative approaches to distance education, including ICT-enabled approaches	• Promote the adoption of partner learning management systems or an equivalent web based platform that can be harmonised for the development of resources, programming and connectivity • Develop a suite of eLearning programs to diversify delivery modality and address multiple learning needs based on international best practice • Recruit strategically for the Office of Cancer Education to ensure a balanced skill mix to support programs of work	• MOOC development - Research and Education Leads online learning program, Survivorship Training for Primary Care Practitioners • Learning Management System • Monday Lunch Live
	• Promote VCCC education and training activities effectively	• Develop an agreed approach to promotion of collaborative VCCC education activities	• Learning Management System • Website • Social media platforms • VCCC Communication strategy
	• Identify external funding opportunities such as philanthropy, sponsorship and government funding to subsidise programming expenditure	• Develop a sponsorship prospectus for all educational programming that can be appropriately supported through external funding	• Sponsorship prospectus • Strategic Research Plan process • Successful applications to the Victorian Cancer Survivorship Program and Graduate Online Melbourne.

		• Invest strategically in the development of new educational programs	
Theme 6 Leadership			
Objective	**Strategy**	**Actions**	**Education and Training Program**
• Lead the VCCC to be a centre for excellence in cancer education and training	• Publish a cancer education and training framework that is relevant, inclusive and useful for the Australian cancer care and research workforce	• Implement programming that supports leadership development in educators such as the Leaders in Cancer program, Research and Education Leads program, leadership professional development and upskilling of individuals in education methodology • Develop tools and provide resources for education and training program evaluation that fosters continuous improvement	• VCCC Education and Training Strategy • VCCC Education and Training Framework • VCCC Leadership program • Research Development and Leadership Program • Specialist Certificate in Clinical Leadership • Resilience workshop • Cognitive Biases in Clinical Decision Making workshop • Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Learning Management System
	• Create cultural change by elevating the status of education to that of research and clinical care	• Implement programming that supports leadership development in educators such as the Leaders in Cancer program, Research and Education Leads program, leadership professional development and upskilling of individuals in education methodology • Establish and support a network of leaders in education across the VCCC alliance • Create formalised guidelines on how to develop and deliver educational programs	• Leaders in Cancer program • Research and Education Leads program and online education program • VCCC Leadership program • Research Development and Leadership Program • Specialist Certificate in Clinical Leadership • Graduate Certificate in Clinical Teaching • Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Educator recognition and reward program
	•	•	•
	• Develop an education and training program to support cancer research and clinical care that is nationally and internationally renown	• Implement programming that supports leadership development in educators such as the Leaders in Cancer program, Research and Education Leads program, leadership professional development and upskilling of individuals in education methodology • Develop a VCCC Office of Cancer Education with in-house capacity to develop, support, deliver	• Leaders in Cancer program • VCCC Leadership program • Research Development and Leadership Program • Specialist Certificate in Clinical Leadership • Resilience workshop • Cognitive Biases in Clinical Decision Making workshop • Graduate Certificate in Clinical Teaching

		and evaluate both face to face and online education and training programming across all partners • Develop tools and provide resources for education and training program evaluation that fosters continuous improvement	• Excellent teaching in no time workshop • Foundation Skills for Surgical Educators • Comprehensive Cancer Centre PhD program • Clinical trials • Translational research and implementation science • Monday Lunch Live • Communication residential program • Research and Education Leads program and online education program ○ Weekend Education Series ○ Survivorship training for primary care practitioners ○ Resistance to cancer therapies in haematology ○ How can I get a nursing-led research project started? ○ Exercise, Physical Activity, and Palliative Care Interventions Across the Spectrum of NSCLC Management ○ Pancreatic Cancer: data and clinical trials / translational research • Oncology Drug Development in Practice • Psycho oncology conference • Survivorship conference • Research conference • Post doctoral symposium • All new programming incl.: • Online education programming for tumour and cross cutting streams • Workforce capacity and capability for clinical trials • Novel trial design • New trial groups • Immunotherapy • Understanding resistance to targeted therapies • Precision Oncology • Precision Prevention • Building nursing research capability for better patient outcomes • Recruitment of new human resources • Learning Management System

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We acknowledge the Traditional Owners of the lands on which we work and pay our respects to their elders past and present.

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The Royal Children's Hospital Melbourne

Western Health

St Vincent's Hospital Melbourne

Austin Health

murdoch children's research institute