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QUT ihbi
Institute of Health and Biomedical Innovation

IHBI ADVANCES

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Professors Ken O'Byrne and Derek Richard


Professor Rik Thompson

Multi-faceted research collaboration brings precision medicine a step closer

Personalised medicine involves medical decisions and treatments being tailored to patients based on a predicted response or risk of disease. The model is benefiting from the growth of new diagnostic and informatics approaches providing understanding of the molecular basis of disease.

IHBI Professor Rik Thompson is leading a large collaboration using genetic analysis, laboratory modelling, clinical trials and patient samples with the aim of enabling personalised cancer therapy.

The collaboration has secured Federal Government support as a Medical Research Future Fund – Rapid Applied Research Translation Initiative, via the Brisbane Diamantina Health Partners, to generate information about prognosis and ultimately guide targeted therapy for personalised cancer management.

Bringing together 12 research and clinical groups working with 3D cultures of tumour material from patients, the initiative aims to identify systems in which the cultured cells best mimic the therapy responses in the patient, so that they could be developed as a predictive, personalised test.

The new Centre for Personalised Analysis of Cancers (CPAC), established to facilitate the collaboration, aims to develop scalable methods suitable for fast-tracking information that clinicians need to direct the identified treatment to individual patients.

IHBI COLLABORATORS

Professors Ken O'Byrne and Derek Richard: **identifying tumours that are responsive to a novel class of therapeutics, enabling development of predictive biomarkers that serve as companion diagnostics for future clinical evaluation.**

Professor O'Byrne and Princess Alexandra Hospital Associate Professor Victoria Atkinson: **immunotherapy clinical trials in solid tumours.**

Associate professors Elizabeth Williams and Ian Vela: **leading the Queensland Bladder Cancer Initiative (QBCI) to tackle multiple aspects of translational research, build resources to improve treatment, provide consumer input and undertake clinical trials.**

CPAC research encompasses 12 major tumour types and involves researchers and clinicians from seven institutions and three Brisbane hospitals.

Importantly, CPAC will promote translational research by providing 16 clinical researcher training fellowships.

Personalised medicine holds great promise for improving clinical outcomes for cancer patients. Professor Thompson says positive clinical outcomes are being observed more generally following treatment with therapies targeting the same specific mutations or gene amplifications – in which cancer cells make multiple copies of genes – across different cancer types.

Immunotherapy, a treatment assisting the body's immune system to fight cancer, is providing such outcomes in about 20 per cent of malignant melanoma patients and in about 40 per cent of non-small cell lung cancer patients who have the appropriate targets.

Professor Thompson says improving the success rates of immunotherapy is likely with better understanding of tumour microenvironments and mechanisms of a cancer's therapeutic resistance.

Developing 3D models of such a tumour microenvironment in a laboratory, using patient samples in the presence of immune cells to closely mimic the actual cancer's behaviour and progression, will enable screening of therapeutics to determine which will be beneficial.

Laboratory models in 3D will also enable CPAC researchers to build a better picture of the genetic character and diversity of the tumours.

The collaboration stems from existing efforts of several IHBI cancer researchers and will leverage the expertise of IHBI bioengineering experts Distinguished Professor Dietmar W Hutmacher, Dr Laura Bray and Associate Professor Michael Doran to build relevant 3D models.

Professor Thompson says an important aspect of the CPAC research is to ultimately ensure that the 3D models rapidly provide clinicians with reliable results so patients can be treated without delay.

'Samples will be accessed from patients at time of diagnosis, and during therapy where possible, to examine dynamic changes linked to therapeutic response from patients undergoing treatment.

'Where possible, the research will include DNA sequencing, a process of comparing healthy and mutated DNA sequences, that has become indispensable in medical diagnosis.'

For that, CPAC researchers will collaborate with IHBI's Australian Translational Genomics Centre (ATGC), under the leadership of Associate Professor Paul Leo, building on its genomic diagnostic service offered to more than 2000 Queenslanders.

ATGC screening identifies cancer-causing genetic mutations and amplifications, leading to improved treatment strategies, potentially fewer side-effects and better survival rates.

Professor Thompson says the CPAC will coordinate avenues for refining the benefits of cancer genetics, identify the most active targeted therapies across a range of cancers, provide useful information for clinicians and ultimately improve patient outcomes.

International bid to improve prostate cancer outcomes

A radical prostatectomy is one option commonly recommended for the management of men with high-risk prostate cancer. IHBI researchers are part of a large international clinical trial that aims to determine if blocking androgen before and after the surgery may improve patient outcomes.


Associate Professor Ian Vela and his team

Associate Professor Ian Vela is collaborating with industry partner Janssen-Cilag as part of a Phase III clinical trial for high risk localised prostate cancer treatment.

The trial aims to determine if a systemic therapy can eradicate micrometastatic disease to improve survival in high-risk participants undergoing radical prostatectomy.

RADICAL PROSTATECTOMY

The removal of the entire prostate gland, the seminal vesicles and the vas deferens. It can be successful in men whose cancer is confined to the prostate.

ANDROGEN

Any natural or synthetic steroid hormone that regulates the development and maintenance of male characteristics. The major androgen in males is testosterone. In addition to their role as natural hormones, androgens are used as medications.

PATHOLOGICAL COMPLETE RESPONSE

The absence of residual cancer—or minimal residual disease—in tissue samples removed during surgery or biopsy after treatment with radiation or chemotherapy. A pathologist checks tissue samples under a microscope for cancer cells after treatment and assesses pathological tumour response to neoadjuvant medication. Knowing if the cancer is in pathologic complete response may help show how well treatment is working.

NEOADJUVANT MEDICATION

Neoadjuvant therapy is the administration of therapeutic agents before a main treatment.

THE CLINICAL TRIAL

A Study of Apalutamide in Participants with High-Risk, Localised or Locally Advanced Prostate Cancer Who Are Candidates for Radical Prostatectomy.

www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=17947&isClinicalTrial=True and https://clinicaltrials.gov/ct2/show/NCT03767244

Micrometastatic disease involves a small collection of cancer cells that has been shed from the original tumour and spread to another part of the body. The cells are too small to be identified using medical imaging.

Androgen deprivation therapy (ADT) will be administered as part of the study, with or without the investigational medicine Apalutamide, before and after the radical prostatectomy – the removal of the entire prostate gland, the seminal vesicles and the vas deferens.

Associate Professor Vela says prostate cancer cells need androgen hormones, such as testosterone, to grow. ADT and the investigational medicine reduce the levels to prevent the cells from growing.

Several studies have concluded that ADT has benefit in patients with metastatic disease, as well as in parallel with radiation therapy in patients with locally advanced disease and those with high-risk localised disease.

Results from earlier Phase II studies show that hormonal treatment before radical prostatectomy may improve outcomes at the time of the surgery and short-term oncological outcomes.

However, the role of ADT combined with newer medicines such as Apalutamide before and after surgery to decrease testosterone to very low levels is unknown – hence the need for trials such as this, Associate Professor Vela says.

The clinical trial includes screening, treatment and follow-up phases, with the primary outcome measures being the percentage of participants with pathologic complete response. Pathological complete response is assessed by central pathology reviewers who evaluate the response – either as no tumour or minimal residual disease.

Secondary outcome measures include the number of participants with adverse events and vital sign abnormalities assessed as part of a physical examination.

A Phase III trial typically assesses the effectiveness of a therapeutic and its value in clinical practice, with multiple trial sites and large patient groups to ensure a definitive assessment of efficacy.

The Janssen-Cilag trial will enrol 1500 participants in 250 locations around the world, including 26 states in the US, 22 prefectures in Japan, 13 states in Germany and 14 provinces in Italy.

Australia has nine sites in three states, with Princess Alexandra Hospital the only one involved in Queensland.

Associate Professor Vela leads activities at the PAH, with dual roles as a urologic oncologist interested in bladder and prostate cancer; and a research team leader at IHBI. He is a principle investigator on multiple clinical trials in both bladder and prostate cancer.

Associate Professor Vela says high-risk localised prostate cancer accounts for about 15 per cent of newly diagnosed prostate cancers.

Prostate cancer is estimated to become the second most commonly diagnosed cancer in 2020, while remaining the most commonly diagnosed cancer among males. It is estimated that 16 741 new cases of prostate cancer will be diagnosed in Australia in 2020.


Associate Professor Jyotsna Batra

DNA risk regions the target for cancer research team

Human DNA consists of 3 billion base pairs of modules, with chemicals that store instructions to direct cell activity. Identifying DNA regions associated with disease risk is a large undertaking, but IHBI researchers lead a collaboration that has shortlisted specific cancer risk regions.

Associate Professor Jyotsna Batra has led a bid for a US Department of Defense Idea Development Grant, with $968 000 to collaborate with clinicians in Canada and researchers from QUT and the University of Queensland. They aim to discover novel molecules believed to be linked to prostate cancer development.

She has used genome-wide association studies (GWAS) to assess thousands of DNA variations in large groups of men and provide insight into the genomic regions that alter risk of developing prostate cancer.

WHAT IS THE HUMAN GENOME?

The total composition of genetic material in a person's cells.

WHAT IS GENETIC VARIATION?

The difference in DNA among people or the differences between populations. Mutation is one source of genetic variation, resulting from DNA being copied and mistakes being made.

HOW DO CELLS MUTATE?

DNA is the molecule found in every cell, containing a person's genetic code and instructing cells what proteins to make.

Proteins form enzymes, responsible for much of the work in cells, and are also an important building block in tissues. They are made in the main body of the cell.

But DNA is only in the nucleus of the cell. A copy of the DNA is made, called a messenger RNA (mRNA), capable of moving through pores in the membrane to the main body of the cell. It is during this copying of DNA that mistakes are sometimes made, resulting in mutation.

With 160 prostate cancer risk regions shortlisted, Associate Professor Batra's research now involves an in-depth analysis of the regions to identify their function, one of which is located on Chromosome 5 and is associated with prostate cancer risk in multiple ethnicities.

'Understanding the functional role of prostate cancer risk-associated genetic variants has the potential to provide insights into the mechanisms driving prostate cancer,' she says.

Despite work to improve patient outcome, median survival for advanced disease patients remains low, she says. 'Therefore, novel approaches to improve patient outcome are a high unmet clinical need.

'Finding a solution for patients is an extremely challenging undertaking. However, it is realistically achievable in the short- to mid-term to identify new genomic targets essential to the progression of prostate cancer.

'It is also our aim to develop innovative targeted therapies that prevent prostate cancer from metastasising; stopping progression of more aggressive, castrate-resistant forms of the disease; and limiting side effects that cause patient suffering.'

The proposed innovative molecules and the developed therapies would then be used in combination with present therapies, with the goal of prolonging patient survival and improving their quality of life.

'Through the genetic association analysis and functional studies, we discovered novel long non-coding RNAs (lncRNA) at Chromosome 5, which is overexpressed in prostate tumour samples compared to the adjacent benign tissue,' Associate Professor Batra says. 'Interestingly, the expression of this lncRNA is correlated with disease aggressiveness and poor progression-free survival in prostate cancer patient samples.'

The lncRNAs are molecules with part or all of a person's genetic material – and are emerging as important mediators in cancer progression and potential therapeutic targets for disease management.

Two therapeutics with United States Food and Drug Administration (FDA) approval to treat other diseases show promise for targeting the lncRNA in prostate cancer patients.

'We anticipate that, pending confirmation in our studies and following preclinical testing, we would take the therapeutics against our lncRNA forward for clinical trials.

'In addition, we will combine highly efficient nanotechnology approaches to deliver the therapeutics that can block the activity of the lncRNA with minimal side effects. Our studies show there is a potential in improving the life of a patient with advanced disease.'

Dr Arutha Kulasinghe

Tumour's treatment response a focus of immunotherapy study

Immunotherapy is increasingly being used in prevention and treatment, stimulating an immune response to enable the body to fight disease, particularly cancer. IHBI researchers are using spatial mapping to determine whether individual patients will benefit from immunotherapy.

Dr Arutha Kulasinghe is a Peter Doherty National Health and Medical Research Council (NHMRC) Early Career Fellow, using funding from Cure Cancer to examine biopsies from patients with head and neck, and non-small cell lung cancers.

He is investigating interactions between tumour and immune cells, which directly influence how tumours respond to immunotherapeutic medicines.

It involves a Nanostring GeoMx Digital Spatial Profiler, secured for IHBI's Kelvin Grove building with support from the Ian Potter Foundation and a generous bequest from the estate of alumni Violet Kuskie.

While immunotherapy is being hailed as a 'game changer' in treating solid tumours, Dr Kulasinghe says there is no way of identifying which patients will respond to the therapy.

'My work aims to comprehensively assess the tumour tissue of the patient,' he says. 'If we can make individualised assessments of a patient's tumour and identify biomarkers for targeted therapies, we're likely to see the greatest benefit.

'My research aims to map tumour and immune cells in the tumour microenvironment, which can be used as a measurable indicator of the presence or severity of disease; an indicator of the risk of disease progression; or of the susceptibility of the disease to a given treatment.'

Biomarkers have so far not been identified for all cancers, such as for head and neck cancer.

Dr Kulasinghe says effective immunotherapy treatment is available for limited numbers of cancer patients.

One of the issues is that many cancer patients are diagnosed when the cancer is too advanced to be treated. Another issue is that cancer cells may change the normal cells around a tumour, interfering with the immune response – or may undergo genetic changes that evade immune system detection.

The immune system detects and destroys abnormal cells, including many cancers. Immune cells are sometimes found in and around tumours – a sign that the immune system is responding. People whose tumours contain the cells often have a better prognosis than people whose tumours do not.

Technological advances enable greater understanding, but there is still a knowledge gap when it comes to the underlying biological interactions between treatments and disease.

Dr Kulasinghe says the Nanostring spatial profiling solution offers a 'GPS to understand the tumour biology' and intricately understand the nuances in the tumour microenvironment which may lead to the identification of biomarkers predictive of outcome to immunotherapies.

The profiler is giving other IHBI researchers the capability to examine cellular interactions and biology with spatial information—and boost understanding of the physiology in tissues such as the liver, bone and brain.

The profiler enables better understanding of molecules in a tissue section. For the first time Australian researchers in liver disease, head and neck cancer, breast, prostate, lung and brain cancer can study tissue regions and predict the responses of targetable therapies.

It will also advance IHBI work in chronic disease and ageing, bone and tissue engineering, and regenerative medicine.

IAN POTTER FOUNDATION SUPPORT: NATHAN SUBRAMANIAM

Professor Nathan Subramaniam led the successful bid for Ian Potter Foundation support for the Nanostring GeoMx Digital Spatial Profiler. He will work with Dr Gautam Rishi, using the equipment to further their research in liver disease and iron disorders. Professor Subramaniam says the equipment has the potential to significantly advance research translation.

OTHER USERS

Associate Professor Chamindie Punyadeera will advance work on non-invasive cancer diagnosis using saliva and liquid biopsy.

Professor Ken O'Byrne will advance his translational work in lung cancer.

VIOLET KUSKIE

Violet graduated in 1942, completing a teaching degree at Kelvin Grove; and returned to studies three decades later, completing a library science degree at Gardens Point in 1976.

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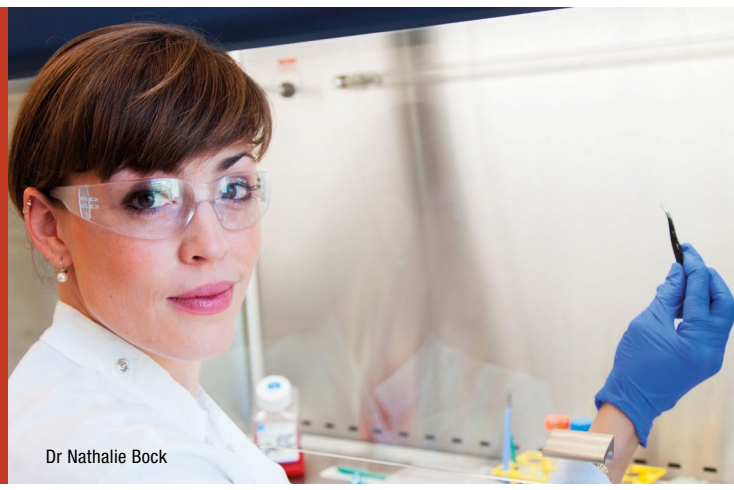
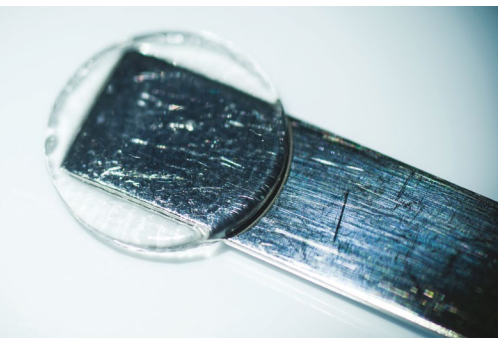
Laboratory models to aid in fast breast cancer decision-making

Breast cancer is not one disease with a single treatment approach. Uncertainty remains about the optimum treatment for a significant number of patients. IHBI researchers are using new models in the laboratory that mimic affected tissue, with the aim of informing clinical decision-making.



Dr Nathalie Bock



Above: A Gelomics hydrogel

Dr Nathalie Bock is collaborating with two industry partners and Brisbane's Mater Hospital, using an Advance Queensland Industry Research Fellowship of $300 000 to develop the 3D printed organoid models to guide individualised therapy.

Sydney industry partner Inventia Life Science brings to the collaboration an ability to rapidly print the organoid models with a patient's own tumour cells, while Brisbane partner Gelomics brings expertise in tailoring them to accurately mimic both soft tissue and bone environments.

The point of difference for the research is an ability to use new printing techniques for high throughput screening, enabling rapid manufacturing and testing of biological samples for activity at the cellular or molecular level.

A focus for Dr Bock is advanced breast cancer involving metastasis to the bone – affecting up to 50 per cent of patients and associated with low survival rates.

She says some patients have pain and side effects requiring orthopaedic surgery, while others have activity in the bone that drives therapeutic resistance.

'Thus, there is a large variety in response, which again remains unaddressed, with no means of personalising preclinical testing,' she says.

'We believe that a high-throughput preclinical model that mimics the bone microenvironment will enable us to screen which patients have the highest potential to metastasise to the bone, informing whether progression to an advanced stage of the cancer may happen – and will help with clinical decisions for patients.

'Knowing the optimum treatment regimen to use would enable the most efficacious combination to be used earlier and would promote survival.'

In addition to rapidly producing breast cancer organoids, the research involves Inventia's 3D bioprinting platform incorporating human bone-forming cells called osteoblasts and Gelomics hydrogels to create models of the bone microenvironment.

Blood is collected and combined with osteoclasts, cells involved in breaking down bone as part of repair and remodelling, to create a preclinical microenvironment for patients scheduled for a mastectomy and lymph node removal.

The work is conducted in IHBI laboratories at the Translational Research Institute (TRI), working alongside researchers from the Australian Prostate Cancer Research Centre – Queensland and the Cancer and Ageing Research Program. TRI is co-located at the Princess Alexandra Hospital to facilitate collaboration with clinicians.

Dr Bock is the lead chief investigator for a Cancer Australia Priority-driven Collaborative Cancer Research Scheme Grant of $199 500; co-chief investigator for an Australian Research Council (ARC) Discovery Project with $601 924 in funding; and co-chief investigator of a $5 million ARC Industrial Transformation Training Centre project.

Her research has been recognised, with a place among the finalists of the Australian Museum Eureka Prize in the Outstanding Early Career Researcher category. The Eureka prizes are a key part of the Australian Museum's role in the nation's scientific research, education and outreach.

'As a dedicated scientist, I value science education highly and hope to be an inspiration and mentor for young children and young women contemplating STEM disciplines,' Dr Bock says.

AUSTRALIAN MUSEUM EUREKA PRIZES AWARDS

Considered the Oscars of science nationally, the Australian Museum Eureka Prizes have been awarded for 30 years.

More than $4 million in prize money and a total of 416 AM Eureka Prizes have been awarded.

The AM Eureka Prizes are a co-operative partnership between government, education and research institutions and the private sector to recognise and support scientific excellence.

Professor Ray Chan

Simple gel shown to help prevent radiotherapy burns

Research ensures an evidence base for healthcare, providing clinicians with the impetus to introduce new processes, techniques or devices. IHBI research provides an evidence base for treating burns from radiation therapy, a painful side effect among head and neck cancer patients.

HEAD AND NECK CANCER:

Occurring inside the sinuses, nose, mouth and salivary glands down through the throat. Although the cancers are different, they are treated similarly.

The main risk factors are alcohol consumption and tobacco.

In 2020, an estimated 5168 people will be diagnosed with head and neck cancer in Australia. The figures include cancers of the tongue, gum, mouth, salivary glands, tonsils, pharynx, nasal cavity and larynx, but not cancers of the lip.

In 2020, there will be an estimated 1151 deaths in Australia.

The five-year survival rate is about 71 per cent.

RADIATION THERAPY:

Radiation therapy or radiotherapy, often abbreviated RT, RTx, or XRT, is a therapy using ionizing radiation, generally as part of cancer treatment to control or kill malignant cells.

RADIATION DERMATITIS:

A common side effect of radiotherapy, with damage to the outer layers of a person's skin.

Symptoms include skin redness, swelling, peeling, thinning, weakening and blistering.

THE PUBLICATION:

A single-blind, randomised controlled trial of a silicone-based film-forming gel dressing for prophylaxis and management of radiation dermatitis in patients with head and neck cancer

www.thegreenjournal.com/article/S0167-8140(19)33004-X/pdf

Professor Ray Chan has conducted the first study to prove a novel silicone-based, film-forming gel dressing is an effective barrier against skin damage from radiation therapy.

He recruited 197 patients with head and neck cancer to show that the gel dressing prevents transdermal water loss during radiotherapy and can reduce radiation dermatitis in patients receiving radical radiation treatment.

His research, published in *Radiotherapy and Oncology*, demonstrates that the gel dressing reduces the risk of developing a wound by 49 per cent in patients receiving radiotherapy for head and neck cancer compared with usual care.

'Many patients with head and neck cancer are offered 'radical' radiotherapy, which is often daily for four to six weeks,' Professor Chan says.

'While radiotherapy has become more and more precise, the radiation goes through the skin 'killing' the skin cells and affecting the skin's ability to rejuvenate itself, ultimately leading to radiation dermatitis – a red, itchy and often painful rash.'

Professor Chan says many clinical studies use topical ointments but none prevent what could be serious wounds requiring burns treatment in head and neck cancer patients.

'The key is to keep the skin hydrated and provide a barrier to avoid further damage,' he says. 'A gel can be reapplied as needed without the problem of a physical dressing falling off.'

Professor Chan says the findings of his research could potentially be applied to anyone undergoing radiotherapy.

'We studied patients with head and neck cancers because they are particularly prone to radiation dermatitis. The skin on the head and neck are in constant movement as the patient goes about their daily life and this means many physical dressings simply fall off and do not provide protection.

'Also, the head and neck areas are often exposed to the sun – and that may worsen the burns.'

Professor Chan says patients should ask their radiation treatment team to access the gel.

Radiation dermatitis causes dry itchy skin in 85 per cent of cancer patients undergoing radiotherapy; and a wet open wound similar to burns that require dressings in up to 15 percent of patients.

EXECUTIVE DIRECTOR'S REPORT

Precision medicine takes into account a person's individual genetic make-up, environmental factors and lifestyle to enable tailored prevention and treatment approaches.

Cancer care stands to benefit significantly from precision medicine approaches, given what we know about the complexity of the disease. For example, some treatments that are effective in the earlier stages cease to be effective as the disease progresses. Others are effective for some people but not others.

Personalised medicine is at the core of much of IHBI's cancer research, as detailed in this edition of *IHBI Advances*.

Professor Rik Thompson is one example, using patientsamples to grow 3D models of their tumour microenvironment, screen therapeutics and determine which will work.

The work involves researchers and clinicians from seven institutions and three Brisbane hospitals to ensure their collaboration has a complete picture of cancer, genetics and the bioengineering needed for the 3D models.

Similarly, **Dr Nathalie Bock** is collaborating with two industry partners and Brisbane's Mater Hospital to develop 3D printed organoid models to guide breast cancer treatment.

Technology underpinning the research enables the models to be tailored so they accurately mimic both soft tissue and bone microenvironments. It also ensured high throughput, enabling rapid manufacturing and testing.

The technology available to **Dr Arutha Kulasinghe** enables examination of biopsies from patients with head and neck cancer, and non-small cell lung cancers, to determine whether they will benefit from immunotherapy. The therapy aims to stimulate an immune response to enable the body to fight disease.

Dr Kulasinghe is investigating interactions between tumour and immune cells to understand response to immunotherapeutic medicines.

Prostate cancer is the focus of research involving **Associate Professor Jyotsna Batra** and **Dr Ian Vela**, with each taking a different approach to arresting metastasis and improving patient outcomes.

Identifying DNA regions associated with disease risk is Associate Professor Batra's approach, collaborating with clinicians in Canada and Queensland researchers to develop targeted therapies that arrest metastasis.

Dr Vela is collaborating with industry as part of a large clinical trial to determine if a systematic therapy can eradicate micrometastatic disease.

Much of IHBI's cancer research involves patient samples – or their active participation. **Professor Ray Chan** has used 197 patients with head and neck cancer to provide an evidence base for using a specific gel for their radiation therapy.

His research gives clinicians an impetus to use the silicone-based, film-forming gel dressing to prevent water loss during radiotherapy and avoid dry, itchy skin.

Cancer is a complex disease, but the breadth of IHBI's research expertise means we are well placed to provide important evidence underpinning future healthcare with a personalised approach and a focus on patient outcomes.

Enjoy this edition of *IHBI Advances*.

Professor Lyn Griffiths
Executive Director, IHBI

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