

Annual Report

2024-2025



ANZUP Cancer Trials Group Limited

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ANZUP acknowledges the Traditional Owners of the lands on which our company is located and where we conduct our business. We pay our respects to ancestors and Elders, past and present. ANZUP is committed to honouring the First Peoples' unique cultural and spiritual relationships to the land, waters and seas and their rich contribution to society. We also acknowledge the Māori people as tangata whenua of Aotearoa New Zealand and as Treaty partners with the Crown as agreed in Te Tiriti o Waitangi.

Act now to accelerate the next research breakthrough

ANZUP stands out due to our unique approach and impact in urogenital cancer research.

Patient-Centred

ANZUP prioritises cancer research outcomes that matter to patients and their loved ones, like quality of life and reduced side effects, in addition to improvements in disease control and overall survival.

Independent. Always.

Research & Trials are driven by clinicians and researchers focussed on identifying areas of clinical need, not commercial interests, fostering independent, high-impact discoveries like the ENZAMET trial.

Multidisciplinary

ANZUP unites over 2,000 professionals – doctors, nurses, clinical researchers, scientists, psychologists, allied health professionals, community representatives and other groups – ensuring diverse perspectives that shape innovative trials.

Seed-to-Success Model

ANZUP's "Below the Belt" Research Grants are aimed at supporting ideas that explore and test innovative ideas that have the potential to impact urogenital cancer where government or industry funding is not available and provide the evidence to support further trials and research that may lead to clinical practice changing outcomes.

Your donation to our Below the Belt Research, no matter how big or small, will ensure that all ideas and avenues have been explored.

Donate Today.

Turn our vision of *Living life without fear of cancer* into reality.

For bespoke support or a confidential discussion, please contact:

Marcel Svatos
Business & Philanthropy Manager
Marcel.Svatos@anzup.org.au

Scan the QR code to donate now.



Every donation over \$2 in Australia or \$5 in New Zealand is tax deductible.

Contents

ANZUP Key Research Milestones 2024-2025	5
Participating Centres	6
Chair's Report	8
CEO's Report	13
About ANZUP.	18-23
Mission, Objective, Priorities	18
Our Goals	19
Research Highlights	24-40
SAC Report	24
Bladder, Urothelial and Penile Cancer Subcommittee	25
Renal Cell Cancer Subcommittee	27
Prostate Cancer Subcommittee	28
Germ Cell Cancer Subcommittee	31
Quality of Life and Supportive Care Subcommittee	32
Translational Subcommittee	33
Imaging and Theranostics Subcommittee	35
Ideas Generation Workshops	37
Consumer Advisory Panel Report	38
Publications, Posters and Presentations Overview/Highlights	40
ANZUP Key Statistics 2024-2025	41
Membership Educational Events	43
Best of GU Oncology Evening Symposium	43
ANZUP 2024 Bladder and Prostate Masterclass	44
Fundraising, Partnerships and Engagement	45
PCFA & ANZUP three-year partnership	45
111 Your Way	45
Melbourne Pedalthon	46
Community Fundraising	46
Grants and Awards.	47-59
Grants and Awards 2024-2025	47
Below the Belt Research Fund	49
Synchrony Fellowship	52
ANZUP / PCFA Partnership Grant	54
Noel Castan Fellowship	55
2024 ANZUP ASM	57
Appendix: Publications, Posters and Presentations	59
Financial Report	61-86
Partners, Corporate and In-kind Supporters	87

ANZUP'S Key Research Milestones 2024-2025

A NEW COMBINATION TREATMENT APPROACH FOR PEOPLE AFFECTED BY **MUSCLE INVASIVE BLADDER CANCER.**
(PCR-MIB)



A NEW COMBINATION THERAPY WITH A DRUG THAT IS USED IN THE TREATMENT OF OSTEOPOROSIS WITH IMMUNOTHERAPY TO FIGHT KIDNEY CANCER.
(KEYPAD)



OVER 2,500 PARTICIPANTS ENROLLED IN A REGISTRY THAT WILL ADVANCE THE UNDERSTANDING OF GERM CELL TUMOURS.
(iTestis)



THE FIRST STUDY OF ITS KIND TO SHOW A CLEAR BENEFIT OF THE RADIOLIGAND THERAPY LUP SMA FOLLOWED BY CHEMOTHERAPY IN ADVANCED HORMONE SENSITIVE PROSTATE CANCER.
(UpFrontPSMA)



A NEW COMBINATION TREATMENT APPROACH THAT IMPROVED OVERALL SURVIVAL AND QUALITY OF LIFE FOR PEOPLE DIAGNOSED WITH HIGH-RISK HARD-TO-TREAT ADVANCED (METASTATIC) PROSTATE CANCER.
(ENZA-p)



PROGRESS TOWARDS ADVANCING NON-INVASIVE KIDNEY CANCER CARE THROUGH PATIENT-CENTRED RESOURCES
(OAK)



A NEW BLOOD-BASED BIOMARKER FOR PREDICTING RESPONSE TO TREATMENT.
(TheraP TRANSLATIONAL RESEARCH)



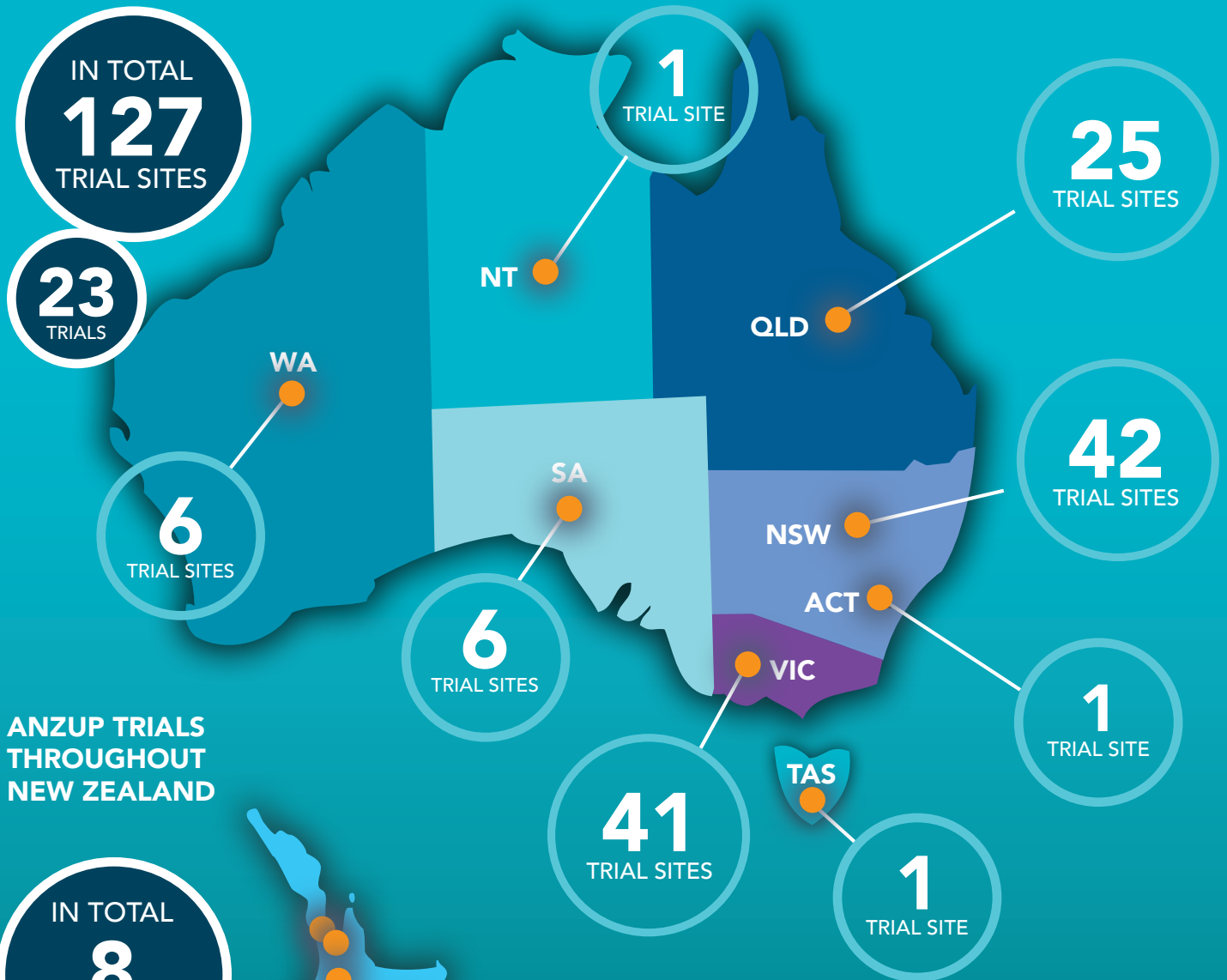
AN EXCITING NEW THREE-YEAR PARTNERSHIP WITH PROSTATE CANCER FOUNDATION OF AUSTRALIA (PCFA) BUILDING ON OUR LONG-STANDING RELATIONSHIP THAT WILL FUEL ADVANCEMENTS NEEDED TO CHANGE THE LIVES OF THOSE AFFECTED BY PROSTATE CANCER.



Participating Centres

Throughout Australia and New Zealand

ANZUP TRIALS IN EVERY STATE AND TERRITORY IN AUSTRALIA



ANZUP TRIALS THROUGHOUT NEW ZEALAND



CURRENT ANZUP TRIALS (23)

BLADDER	TESTICULAR	PROSTATE	KIDNEY
G-DISCO	P3 BEP	ANZadapt	ENZAMET*
BCGMM*	CLIMATE	GenI-AIRSPACE	ENZARAD*
PCR-MIB*	TIGER*	WOMBAT	ENZA-p*
		EVOLUTION*	proPSMA*
		DASL-HICAP*	NINJA
			UpFrontPSMA*
			KEYPAD
			UNICAB
			RAMPART
			UNISoN*
			FASTRACK II*

* TRIALS IN FOLLOW UP

CO-BADGED STUDIES

Participating Centres

Across the rest of the world

IRELAND

4

TRIALS

13

TRIAL SITES

UK

6

TRIALS

23

TRIAL SITES

CANADA

3

TRIALS

30

TRIAL SITES

AUSTRIA

1

TRIAL

1

TRIAL SITE

SLOVENIA

1

TRIAL

1

TRIAL SITE

BELGIUM

1

TRIAL

1

TRIAL SITE

USA

39

TRIAL SITES

6

TRIALS

SPAIN

1

TRIAL

3

TRIAL SITES

IN TOTAL

131

TRIAL SITES

8

TRIALS

Chair's Report

BY IAN DAVIS,
DIRECTOR AND CHAIR OF
THE ANZUP BOARD



IAN DAVIS

It is my honour and privilege to present the ANZUP Cancer Trials Group Annual Report for 2024-2025 to you on behalf of the Board.

ANZUP is a not-for-profit company and a registered charity in all Australian states and territories and in New Zealand. This Annual Report details the corporate activities of the Company as well as its scientific, educational, and social activities and outcomes.

ANZUP continues to grow in size and productivity, as we strive towards achieving our mission of improving the lives of people affected by bladder, kidney, testicular, penile, and prostate cancers.

We are centred on developing and conducting clinical trials of the highest quality, that will answer the needs that we and the community face every day with these diseases. We are conscious that we have multiple stakeholders: our funders, donors, supporters, collaborators, researchers, clinicians; and most importantly the wider community that we serve and whose needs speak to us most profoundly. ANZUP has a responsibility to make a difference, and we are proud that we have done so and will continue to do so, while recognising there is much yet to be done.

Clinical trials are a large part of what we do, but we know that this work requires substantial support systems and people, especially as ANZUP matures and takes on more functions in clinical trial sponsorship and operations, together with its partners and collaborators. We must also secure our future viability: not only financially, but to ensure there is a steady stream of new ideas and new people, effective support for those already with us, training and mentorship for those who will lead us in the future, systems to allow effective two-way communication with the wider community, and mechanisms to implement our research findings to improve health care

policy and practice. We need to be able to do all these things collegially and in careful consultation, while at the same time not allowing processes to bog us down. Delays in achieving our goals equate to missed opportunities to reduce death and disease burden for the people we serve.

The corporate aspects of ANZUP are overseen by its Board, which works closely with our Chief Executive Officer and the ANZUP staff. The Board ensures we meet all our financial, fiducial, and other compliance responsibilities. Subcommittees of the Board oversee Finance and Audit, Fundraising and Partnerships, and Governance matters. The scientific strategy is driven through the Scientific Advisory Committee and its subcommittees, which are comprised of diverse communities of clinicians, researchers, and community representatives. This structure ensures we have input from all the necessary perspectives, including the imperatives identified by the wider community. It allows effective two-way communication to the various disciplines and groups represented; provides opportunities for regular review of the clinical and scientific landscape; and ensures expertise and rapid responses to allow us to evaluate and undertake new ideas and opportunities.

ANZUP and its collaborating partners provide systems for oversight of all of ANZUP's trials. Each trial has its own governance structure, including a Trial Management Committee Trial Management Committee, comprising lead investigators, ANZUP staff, and coordinating centre staff. A Trial Executive Committee is a smaller group charged with managing the day to day operations and decision making for each trial. Some of our trials involve international sites, in which case we have instituted other oversight mechanisms such as International Trial Steering Committees for each relevant study; these ensure engagement of our collaborating groups and centres as well. ANZUP has established an Independent Data Safety and Monitoring Committee to ensure that independent and unconflicted expert oversight is available. We are very grateful to all who contribute to these processes.



ANZUP CAP AT THE 2024 ASM.

ANZUP is particularly grateful to and proud of its Consumer Advisory Panel. The CAP has representation at every level of ANZUP, ensuring that the community voice is always heard and represented. Our CAP works tirelessly to oversee trial development and implementation, as well as ongoing review of documentation, participation in grant applications, and invaluable input to our educational and other activities including our Annual Scientific Meeting. They all bring considerable expertise of their own and generously donate their time and energy to ensure ANZUP is continually provided with the best possible support and advice. The CAP's input is far more than one or two voices in a meeting; it has particular weight and significance that requires specific consideration in the light of our strategy and the community's needs, and we ensure that such input is appropriately incorporated and valued. The Board is immensely grateful to everyone who contributes to the CAP, the SAC, and in so many other ways to what we do.

Our CEO, Professor Samantha Oakes, has now been with us for just over 12 months. It is always an imposing responsibility to step into the well-worn shoes of a predecessor and be able not only to continue previous success, but to build upon it and bring new value. Sam has taken on this challenge with cheerful enthusiasm and has been highly effective. She has worked closely with the Board to set up new systems in the ANZUP office and with its staff, and also has brought new perspectives that have been invaluable in our future planning. One example was how Sam and the ANZUP team have worked together with the Board to review our structures and to develop a Strategic Plan to refresh the previous plan that has now expired. This new Strategic Plan was endorsed by the Board in March 2025 and you will now be able to see the rollout of its implementation. ANZUP is fortunate to have an executive team and staff of such high quality.



The Strategic Plan 2021-2024 included five strategic goals, and we have continued to address them. Examples are as follows:

1 Conduct high quality, multidisciplinary, practice-changing clinical trials in urogenital cancers.

The last 12 months have seen ANZUP featured prominently on the global stage, often including literal stages. We opened the GenI-AIRSPACE, WOMBAT, and G-DISCO studies. Data were presented for ENZAMET, P3BEP, UNICAB, UpFrontPSMA, and ENZA-p. We had publications for TheraP, UpFrontPSMA, ENZA-p, SUBDUE-3, and UNISoN, with other manuscripts in various stages of preparation or submission.

2 Maintain a portfolio of trials relevant to and accessible by all people with urogenital trials in Australia and New Zealand.

This continues to be a challenge due to the limited opportunities for successful competitive grant funding. A large pipeline of ideas continues to flow through our committees and workshops. ANZUP works with industry partners and through philanthropy and fundraising to secure alternative sources of funding. We are aware that inequities remain across the clinical trials sector and our aim is to provide opportunities wherever possible to address those inequities. A new initiative planned for 2025 will be an Ideas Generation Workshop to be held in New Zealand specifically to produce ideas for studies that can be run in New Zealand. The Board sets aside discretionary funding in the budget to support work that is of high priority but for which funding might not be available, or for which timelines of funding are uncertain. An example for this year is commitment to support initiation of the Outcomes of Australians with Kidney cancer (OAK) program, led by CAP chair Belinda Jago. We will continue to investigate other creative approaches to support the growing needs of underserved or underrepresented communities.

3 Strengthen ANZUP's capacity for practice-changing clinical trials.

The ANZUP team has continued to grow, bringing in staff with expertise in trial management and enhancing our ability to sponsor clinical trials. We have effective partnerships with coordinating centres such as The George Institute for Global Health and the NHMRC Clinical Trials Centre, which further expand our ability to perform the trials that need to be done. Our Consumer Advisory Panel members constantly examine new proposals as they are presented, and provide us with advice on whether they will meet the community's needs. Our goal is to perform work of outstanding quality that will make real and positive differences in the lives of all people affected by genitourinary cancers.

4 Forward plan to maintain a vibrant and active urogenital cancer trials community.

This is essential if ANZUP is to continue to grow and thrive. The Board, the executive team, and the Scientific Advisory Committee have recognised this and are developing new processes for implementation as part of our revised strategic plan, in order to maximise engagement by our members and to provide more opportunities for people to take up leadership roles. We will also continue to provide learning opportunities, including our Ideas Generation Workshops, the MDT Masterclass held at the Annual Scientific Meeting, our Best of GU events, and our Rapid Fire Masterclass, all of which were once again highly successful and well attended this year.

5 Provide leadership in collaborative cancer clinical trials.

ANZUP has become synonymous with well-designed, impactful, and clinically meaningful clinical trials, frequently mentioned and commended by others at meetings and in editorials. We will only make a lasting and effective difference if our work continues to address clinical needs as identified by the research community and the wider community. We have forged relationships with other groups in Australia, New Zealand, and internationally, to ensure this type of activity can continue to thrive and that ANZUP and its members are active participants and leaders.

Our new strategic plan for 2025-2028 is based on four Strategic Pillars. You will read more about these elsewhere and see the plan enacted in coming months. Briefly, the Strategic Pillars for 2025-2028 are:



Cancer Research. This is our core business and is continually evolving and expanding.

Reach and Relevance. This takes into account an external focus on our position in the clinical and research community, our drive for inclusivity and diversity in our research, and our relevance in the local and global community.

Capacity Building and Sustainability. This is more internally focussed, with consideration of our financial sustainability, provision of resources, engagement with our membership, and building of future research capacity of the organisation and its members.

People and Partnerships. This ensures we continue to be guided by our culture and our values, with consideration of those working within ANZUP, and growth in productive partnerships externally.



MELBOURNE PEDALTHON

The past 12 months have seen some old initiatives continue to thrive, some that have undergone change, and some new ones that have opened up exciting new opportunities. We once again held Ideas Generation Workshops for our various subcommittees, leading to a steady stream of new ideas and newly engaged members. These workshops allow diverse input into nascent projects and give opportunities for mentored development of the ideas. Not all will eventuate into ANZUP trials, but some will lead to other projects, and all those involved in the process benefit from listening to and learning from others. We have continued our educational initiatives, including our highly successful Annual Scientific Meeting held in July on the Gold Coast, and the Best of GU Update held in Sydney in November. A Renal Cell Carcinoma Masterclass is in planning for May 2025.

The Melbourne Pedalthon was held in 2024 but the difficult decision was then made to cancel the planned Sydney event. All initiatives like this have a finite life cycle, and it had become clear that the Pedalthons, while very popular and great opportunities to raise awareness for ANZUP and its activities, were no longer going to be financially viable. The Below the Belt Pedalthons were the brainchild of Simon Clarke, a tireless supporter of ANZUP and its activities. We are deeply grateful to Simon, his family, and everyone involved in the Pedalthons over the 10 years of its existence. Over two million dollars have been raised to support the Below the Belt Research Grants, providing much-needed support for 36 researchers and projects that would not otherwise have been possible.

The Board recognises the importance of continuing to support the Below the Belt Research Fund, and has continued to earmark resources for this initiative. The 111 Your Way Below the Belt fundraising initiative was inaugurated in 2024 and we will continue to refine and evolve this and other initiatives to secure an ongoing revenue stream for this work. The Board has also provided resources for discretionary funding for various initiatives over the last few years. ANZUP has also facilitated new fellowships, and 2024 was no exception with the 2024 Synchrony Fellowship awarded to oncologist and geriatrician Dr Wee-Kheng Soo, to develop a frailty index based on quality of life data. We are grateful to the Synchrony Foundation for this generous and very impactful support.



SIMON CLARKE @ SYDNEY PEDALTHON



DR WEE-KHENG SOO RECEIVED THE #ANZUP24 SYNCHRONY FELLOWSHIP FOR HIS PROJECT ON FRAILITY AND QUALITY OF LIFE IN PROSTATE CANCER.

A particularly exciting initiative this year was the signing of a new agreement with Prostate Cancer Foundation of Australia (PCFA). PCFA has been a staunch supporter for ANZUP since our inception. This new 3-year agreement guarantees substantial funding from PCFA to support ANZUP prostate cancer clinical trials, and brings our two organisations into even closer alignment and partnership. You will start to see the tangible outcomes of this partnership in the very near future.

Our scientific productivity continues to grow, as evidenced by recent conference presentations, and a record eight abstracts submitted to the 2025 American Society of Clinical Oncology Annual Meeting of which four will be oral presentations. We continue our highly productive relationships with other groups such as the University of Sydney NHMRC Clinical Trials Centre, The George Institute, the University of Melbourne Biostatistics and Clinical Trials Centre, the Hunter Medical Research Institute; and others for specific projects. We welcomed a new Fellow, Nadia Hitchen, in partnership with the Walter and Eliza Hall Institute.

This Annual Report contains detailed financial information and the outcomes of our annual audit, which was once again very positive. ANZUP's finances continue to be in a very healthy state. We are well placed to meet our obligations as and when they fall due. Surplus funds are carefully invested into an ethically sustainable investment portfolio, managed through Perpetual. ANZUP is a careful steward of its financial resources, with plans to use them to support its mission. Our current main revenue streams comprise the following:

- **Infrastructure support through the Cancer Australia Support for Cancer Clinical Trials program.** We were delighted to have confirmation that this funding will continue at least until mid 2027.
- **Annual Scientific Meeting.** This has become a very important genitourinary cancer scientific meeting on the international calendar. It usually attracts over 400 delegates and generates revenue for ANZUP through sponsorship and registrations. The theme for the 2024 meeting was "Making Waves," acknowledging the Gold Coast location, and also acknowledging that the ride is sometimes not smooth, and that we can have positive disruptive effects (and enjoy ourselves while doing so). The theme for the 2025 Annual Scientific Meeting in Sydney is "Listen, Reflect, Connect" – good advice, and a good description of what we hope to achieve in this meeting and in our broader activities.

- **Corporate supporters.** We are very grateful to various industry partners who generously support our activities through untied contributions to our corporate supporter program, as well as specific sponsorship of various events, meetings, and scholarships or awards. Our federal funding means some constraints on the ways we can engage with industry, and ANZUP is careful to do so while also ensuring that our supporters receive value for what they provide. We are glad that the feedback we receive about these partnerships is uniformly positive, and that ANZUP is seen as an organisation with which others want to work.
- **Fundraising.** Our team is currently reviewing and revising our strategy, as we transition away from the Pedalthons and explore more initiatives that may be more productive and accessible. The Board will continue to support the Below the Belt Research Fund.
- **Philanthropy.** We held a meeting late in 2024 with experts in this field and this has led to a number of new initiatives that we hope will bear fruit in the long run. We recognise that financial donations are valuable and important, and allow us to do the work we need to do. We also recognise the extraordinary value of the donations of time and expertise made by so many to support ANZUP and its activities.

It has been an exciting, eventful, productive, challenging, and rewarding year for ANZUP. I am immensely grateful to our Board of Directors, our ANZUP staff under Sam Oakes' leadership, and to all our members, supporters, collaborators, and partners. ANZUP's newly updated vision statement is

"Living life without fear of cancer."

Every word of that statement speaks profound volumes. Imagine a world where we can achieve that. Imagine what that will mean for our patients, those who love them, those who provide healthcare for them, and those who generate the knowledge we need to improve their lives. And then realise, and celebrate, that ANZUP continues to move closer every day to making that vision a reality.

I commend to you this 2024-2025 Annual Report of ANZUP Cancer Trials Group.

Ian Davis
Director and Chair of the ANZUP Board

CEO's Report

BY SAMANTHA OAKES,
CHIEF EXECUTIVE OFFICER,
ANZUP

ANZUP CEO SAMANTHA OAKES SHARING 'WHAT'S UP AT ANZUP' AT THE USANZ 2025 ASM.



SAMANTHA OAKES

At ANZUP, our mission is to improve the lives of people affected by bladder, kidney, testicular, penile, and prostate cancers towards our vision of living life without fear of cancer. Our vision of living life without fear of cancer is ANZUP's commitment to following through and achieving our goals. This is also my commitment to all of you.

In my first year as CEO, I'm incredibly proud of the significant strides we've made. Our work continues to earn global recognition, reflecting the transformative impact of our research. With 35 clinical trials spanning completion, development, active recruitment, and follow-up, and over 10,000 participants across 131 sites worldwide, our reach and influence are truly extensive. Our cancer consumer-focused approach ensures that every aspect of our cancer research, from our trials through to our translational research prioritises outcomes that are relevant to people affected by a Below the Belt cancer, in terms of survival but also quality of life.



This past year has been marked by remarkable milestones, driven by the unwavering dedication of our members. Key cancer research highlights include:

- A new combination treatment approach for people affected by muscle invasive bladder cancer. (PCR-MIB)
- A new combination therapy with a drug that is used in the treatment of osteoporosis with immunotherapy to fight kidney cancer. (KEYPAD)
- Over 2,500 participants enrolled in a registry that will advance the understanding of Germ Cell Tumours. (iTESTIS)
- The first study of its kind to show a clear benefit of the radioligand therapy LuPSMA followed by chemotherapy in advanced hormone sensitive prostate cancer. (UpFrontPSMA)
- A new combination treatment approach that improved overall survival and quality of life for people diagnosed with high-risk hard-to-treat advanced (metastatic) prostate cancer. (ENZA-p)
- Progress towards advancing non-invasive kidney cancer care through patient-centred resources. (OAK)
- A new blood-based biomarker for predicting response to treatment. (TheraP translational research)
- An exciting new three-year partnership with Prostate Cancer Foundation of Australia (PCFA) building on our long-standing relationship that will fuel advancements needed to change the lives of those affected by prostate cancer.

ANZUP is driving progress in Below the Belt cancer research by expanding its portfolio of high-quality and cutting-edge cancer research providing access to life-improving interventions via our clinical trials and better understanding of disease through our translational research program. We anticipate launching several innovative studies in 2025/2026 as we continue to grow and increase our impact for those affected by a Below the Belt cancer.

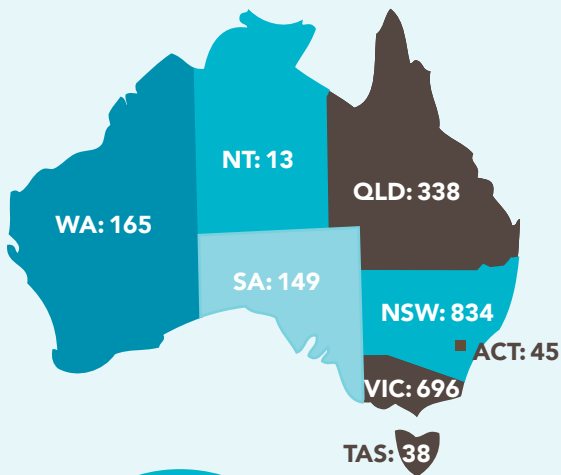
Our Strategic Plan emphasises our multidisciplinary approach with collaboration at the heart of everything we do, integrating an understanding of what is important to those with a lived experience of cancer with the assistance of our Consumer Advisory Panel (CAP) from the inception of a research idea through to the dissemination of the research findings. Ideas Generation Workshops are fundamental to this process, providing a platform to analyse treatment evidence, identify research gaps and areas of unmet clinical need, and ensure consumer-focused trial design and research. These workshops offer vital training for emerging researchers, including fellows, trainees, and junior researchers. As of March 31, 2025, our membership has grown to over 2,500, demonstrating the strength of our collaborative network.

In mid-2024, ANZUP secured funding from the Australian Federal Government via Cancer Australia’s Support for Cancer Clinical Trials Program, ensuring vital infrastructure support until September 30, 2027, a program that contributes to the delivery of the Australian Cancer Plan, designed to increase the number of clinical trials in Australia, increase participation and enhance equitable access to cancer care, especially in rural and remote areas and Aboriginal and Torres Strait Islander communities.



Membership distribution

by State/Territory in Australia:



2,278

TOTAL MEMBERS
IN AUSTRALIA

Rest of the world:

Argentina	1	Kenya	1
Belgium	2	Korea	1
Canada	9	Malaysia	23
China	1	Nepal	1
Denmark	1	New Zealand	136
Ethiopia	1	Pakistan	1
France	1	Phillipines	1
Germany	3	Singapore	5
Hong Kong	1	Spain	1
India	7	Sweden	1
Indonesia	2	Switzerland	1
Iran	4	Turkey	1
Ireland	7	UK	9
		US	23

245

TOTAL MEMBERS
ACROSS THE REST
OF THE WORLD:



#ANZUP24 ASM ON THE GOLD COAST

Our 2024 ASM in the Gold Coast brought together 485 multidisciplinary healthcare professionals; doctors, nurses, allied health care professionals, scientists, researchers, and community representatives. Over 80 speakers, panellists, session chairs, and poster presenters, including a stellar international faculty, fostered collaboration and knowledge exchange across GU cancer disciplines.

We are grateful for the support of our community to help us advance towards our mission to improve the lives of those affected by Below the Belt cancers. This year we celebrate our fundraising success with our Melbourne Pedalthon, held at Sandown Racecourse on April 21, 2024, raising over \$43,000. The Below the Belt 111 Your Way campaign, held throughout October, and the Christmas appeal raised nearly \$25,000 combined. We are also proud of our partnership with the Sydney Sock Project, with our Below the Belt socks raising over \$14,000 since its launch in 2023. We look forward to continuing to build partnerships with our community of supporters as we look to expand our life-improving impact.

Strategic & Business Planning

ANZUP celebrates the success of our 2022-2024 Strategic Plan, which concluded at the end of 2024 and aimed to:



- Conduct high-quality, multidisciplinary, practice-changing clinical trials in urogenital cancers



- Maintain a portfolio of trials relevant to and accessible by all people with urogenital cancers in Australia and New Zealand



- Strengthen ANZUP's capacity for practice-changing clinical trials



- Forward plan to maintain a vibrant and active urogenital cancer trials community



- Provide leadership in collaborative cancer clinical trials

Driven by our mission, ANZUP delivered on these strategic objectives, supported by our dedicated community and membership. Key to our success was our robust governance framework, overseen by our Board of Directors and expertly led by ANZUP's Chair and founder, Professor Ian Davis. The ANZUP Board committees include the Finance and Audit Committee that helps the Board fulfil its financial and risk management responsibilities, the Scientific Advisory Committee that provides advice on clinical and translational research priorities, the Fundraising and Partnerships Subcommittee that identifies and pursues opportunities to raise awareness and additional revenue to support ANZUP achieve its mission and the Consumer Advisory Panel that contributes to all levels of governance to address the needs of those with a lived experience of cancer. The Subcommittees (by disease type and non-disease specific area) advice the scientific advisory committee and helps to inform the areas of greatest need among disease types and non-disease specific areas, Trial Management Committees, operations executive and independent data safety monitoring committees ensure that our clinical research maintains robust scientific rigor and safety.

With the conclusion of ANZUP's current Strategic Plan at the end of 2024, development of ANZUP's new 2025-2028 Strategic Plan, led by the ANZUP Board of Directors and informed through a broad consultation with the ANZUP Leadership Team, employees, Scientific Advisory Committee, sub-committees, membership, Consumer Advisory Panel and other stakeholders. The strategy will be implemented from 1 April and will serve as our plan to deliver on our mission to improve the lives of people affected by bladder, kidney, testicular, penile and prostate cancers towards our vision of living life without fear of cancer. Guided by our values – Commitment, Collaboration, Integrity, Respect, and Agility – we will focus on activities within four strategic pillars: Cancer Research, Reach and Relevance, Capacity Building and Sustainability, and People and Partnerships intended to support ANZUP's sustainable growth across our cancer research portfolio. With your support, we are dedicated to the successful implementation of this plan and progress towards our vision. We look forward to sharing the details of the 2025-2028 Strategy in the coming year and working with all of you to deliver on the plan.

Finances

ANZUP acknowledges the Australian Government's infrastructure funding through Cancer Australia. While crucial, trial-specific funding remains essential. ANZUP prioritises financial autonomy via diversified funding streams that include responsible investments and through philanthropy and fundraising. We thank our corporate supporters, sponsors, and donors for their contributions and we are particularly grateful for the support of our long-term partner Prostate Cancer Foundation of Australia, with our new three-year partnership announced in October at Parliament House, Canberra aimed at accelerating clinical trials and advancements in prostate cancer treatment. Detailed financials are available in the financial report.

Data quality and integrity

ANZUP collaborates closely with coordinating centres to establish robust trial processes, including the NHMRC Clinical Trials Centre (CTC) at the University of Sydney, the George Institute for Global Health (TGI) at UNSW Sydney, the Centre for Biostatistics and Clinical Trials (BaCT), the Walter and Eliza Hall Institute of Medical Research (WEHI) and the Hunter Medical Research Institute (HMRI).

Quality management systems, standard operating procedures (SOPs), and templates ensure trial accuracy. Meticulous data system planning, monitoring, and audits guarantee reliability. Annual site staff training maintains data quality, adhering to national and international guidelines. An Independent Data and Safety Monitoring Committee reviews trial safety and efficacy, reporting to the ANZUP SAC Chair and the relevant

Trial Management Committee. ANZUP's trial and research governance processes and oversight ensures ANZUP's research quality and integrity is maintained to the highest standards to maximise our impact for those affected by the cancers we treat.

ANZUP staff commitment

We express our gratitude for the management team's dedication and commitment to supporting members and stakeholders, ensuring expertise across key operational areas. We extend sincere gratitude to ANZUP Fellows Dr Carole Harris (ANZUP/TGI Senior Research Fellow), Dr Anthony Uccellini (ANZUP/WEHI Research Fellow), and Dr Nadia Hitchen (ANZUP/WEHI Research Fellow). We acknowledge the contributions of Anthony, whose fellowship concluded in early 2025 and we are thrilled to welcome Nadia, our new ANZUP/WEHI Research Fellow, who joined us in 2025. Nadia is a junior medical oncologist with recent training in Auckland and Melbourne and brings a passion for urogenital cancer research and collaboration.

Education and mentoring

ANZUP enhances member education and mentoring, fostering the next generation of clinical leaders and researchers.

Throughout 2024 and 2025, we held 6 Ideas Generation Workshops with 149 attendees and 35 new trial and research ideas presented and discussed with our multidisciplinary members. These workshops are important to grow and foster a pipeline of innovative ideas to be considered and prioritised with support from ANZUP moving forward.



PROSTATE CANCER IDEAS GENERATION WORKSHOP LED BY PROF LISA HORVATH AND PROF JARAD MARTIN, WITH OVER 10 RESEARCH CONCEPTS PRESENTED.



BEST OF GU EVENING SYMPOSIUM IN SYDNEY, CONVENED BY PROF IAN DAVIS AND DR CAROLE HARRIS.

We held our Best of GU Evening Symposium on Wednesday, November 20, in Sydney. The Best of GU is a collaboration between ANZUP and the Urological Society of Australia and New Zealand (USANZ). It featured highlights from 2024 meetings, including the latest management and clinical trials research in urogenital and prostate cancers. Prof Ian Davis and Dr Carole Harris were the convenors, and we had a great lineup of speakers.

The Bladder and Prostate Masterclass Program was held in Sydney on November 28 and 29 and featured a multidisciplinary educational program convened by Dr Tahlia Scheinberg and Dr Cam McLaren. The 1½-day workshop was designed to help trainees develop their clinical trial ideas in bladder and prostate cancer and was a huge success!



DR TAHLIA SCHEINBERG AND DR CAM MCLAREN LED THE BLADDER AND PROSTATE MASTERCLASS IN SYDNEY.

Collaborations and partnerships

ANZUP values strong national and international research collaborations, facilitating improved patient outcomes. We appreciate our investigators, trial staff, and coordinating centre partners (CTC, TGI, BaCT, WEHI, HMRI) for their continuing commitment to helping us deliver on our mission.

Deepest gratitude to corporate supporters, sponsors, and donors for their continuous generosity and support. We sincerely thank the thousands of patients whose participation enables ANZUP's mission to advance Below the Belt cancer treatments.

As I reflect on my first year as CEO, I'm filled with immense pride. We've achieved incredible progress towards our vision, and I have been privileged to witness the unwavering commitment of our members, partners, and the entire ANZUP community. I continue to be humbled by remarkable dedication of the ANZUP family, modelled by ANZUP's Chair, Professor Ian Davis, who personifies ANZUP's values of commitment, collaboration, respect, integrity and agility. ANZUP would not be the organisation it is without Ian, and I am absolutely honoured to work alongside him, the Board of Directors and the rest of the ANZUP community. My sincere thanks go out to all of you for welcoming me into the ANZUP family this past year. This first year has set a strong foundation and as we forge ahead to ensure future growth and sustainability under our 2025-2028 Strategic plan, I'm enthusiastic about the future growth of ANZUP to deliver improved outcomes for those affected by bladder, kidney, testicular, penile and prostate cancer. One hundred and thirteen people are diagnosed with a Below the Belt cancer in Australia and New Zealand every day, and while we have made incredible progress with improved treatments and interventions that improve survival and quality of life for those affected, we have so much more work to do. Together with all of you, I remain committed to continuing to deliver on our mission towards our vision of living life without fear of cancer.

I commend ANZUP's 2024/2025 Annual Report to you.

Adjunct Professor Samantha R. Oakes
Chief Executive Officer, ANZUP

Our Mission

ANZUP's mission is to improve the lives of people affected by bladder, kidney, testicular, penile and prostate cancers through practice-changing multidisciplinary collaborative clinical trials.

Our Objectives

We do this by:

- Bringing together clinicians, scientists and consumers to identify critical areas of unmet need that can be addressed through research in Australia and New Zealand
- Providing a collaborative forum to generate research ideas and concepts that address critical clinical questions
- Providing services and resources to support and fund research of the highest quality
- Promoting access to clinical trials for all people affected by urogenital cancers in Australia and New Zealand
- Mentoring and building the skills of future research leaders
- Securing government, industry and philanthropic funding to facilitate our independent research agenda
- Promoting our research goals and progress to improve clinical practice and change lives.

ANZUP Strategic Priorities:

Our Goals 2021-2024



Goal 1: Conduct high-quality, multidisciplinary, practice-changing clinical trials in urogenital* cancers



Goal 2: Maintain a portfolio of trials relevant to and accessible by all people with urogenital cancers in Australia and New Zealand



Goal 3: Strengthen ANZUP's capacity for practice-changing clinical trials



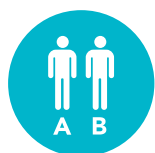
Goal 4: Forward plan to maintain a vibrant and active urogenital cancer trials community



Goal 5: Provide leadership in collaborative cancer clinical trials

* Kidney, bladder, prostate, testis, penis

Our Goals



Goal 1: Conduct high-quality, multidisciplinary, practice-changing clinical trials in urogenital cancers.

ANZUP unites healthcare professionals, researchers, and patients affected by genitourinary (GU) cancers, driving clinical trials and research across GU cancer types (prostate, kidney, bladder, testicular, and penile). Trials explore diverse treatments, including nuclear medicine, immunotherapy, and supportive care. Multidisciplinary Principal Investigators (PIs) from various specialties (medical oncologists, radiation oncologists, oncology, nursing, psycho-oncology, scientists, clinical trial staff etc) lead these efforts.

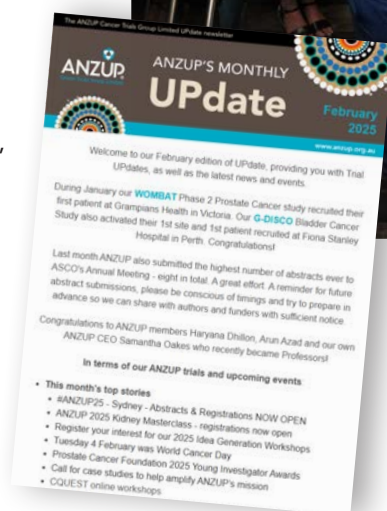
We foster the next generation of researchers through events like ANZUP's Best of GU Oncology Evening Symposium, Bladder and Prostate Masterclass, Annual Scientific Meeting (ASM), and our Idea Generation Workshops (IGWs). Subcommittees regularly analyse trial progress and the research pipeline, providing quarterly updates. Cancer-specific IGWs encourage new concept development.

ANZUP keeps members informed about trials through multiple channels, including the Monthly Trial UPdate, which highlights trial recruitment, upcoming events, and key trial updates to improve patient recruitment and cross-referrals. Regular updates are also provided via the ASM, trial specific e-newsletters, social media, website, and Trial Management Committee (TMC) meetings.

ANZUP actively collaborates internationally, including on trials like ENZAMET, ENZARAD, and DASL-HiCaP, hosting biannual International Trial Steering Committee meetings. These meetings foster relationships within the international clinical trial community, analyse the GU trial landscape, identify research gaps, and explore new concepts. Internally, the Scientific Advisory Committee (SAC) fosters innovative trial ideas and develops them into impactful research protocols.



ABOVE: THE BLADDER AND PROSTATE CANCER MASTERCLASS TOOK PLACE IN SYDNEY IN NOVEMBER 2024.



LEFT: ANZUP'S MONTHLY UPDATE.



ACTIVELY INVOLVED IN ALL RESEARCH INITIATIVES, CAP MEMBERS ATTENDED THE #ANZUP24 ASM ON THE GOLD COAST.



Goal 2: Maintain a portfolio of trials relevant to and accessible by all people with urogenital cancers in Australia and New Zealand.

ANZUP actively promotes trial awareness, participation, and access through diverse channels, fostering a growing membership across all GU cancer types. We encourage attendance at subcommittee meetings, welcoming both regular members and newcomers, including colleagues and trainees.

ANZUP also engages externally at meetings like the Australia and New Zealand Urological Nurses Society (ANZUNS), the USANZ New Zealand Section Meeting, and COSA to highlight membership benefits.

Throughout the year, ANZUP trials involved 9 rural/regional sites, with 73 patients recruited and in follow-up. Rural members and their patients are regularly invited to contribute to our clinical newsletter and UPdate.

Patient and caregiver perspectives are central to ANZUP's work. The Consumer Advisory Panel (CAP), reflecting diverse GU cancer types, is actively involved in all research initiatives, from the SAC and subcommittee meetings to IGWs and the ASM.

Actively involved in all research initiatives, CAP members attended the #ANZUP24 ASM on the Gold Coast.

ANZUP also connects with the broader community through various social media platforms: X (formerly Twitter), BlueSky, Facebook, Instagram, LinkedIn, and YouTube, sharing information about our activities, events, and clinical trials.

Subcommittee	Total Members							
	Mar 2018	Mar 2019	Mar 2020	Mar 2021	Mar 2022	Mar 2023	Mar 2024	Mar 2025
Prostate	442	493	531	579	668	724	730	759
BUP	302	335	367	395	423	459	449	467
Germ Cell	190	209	230	246	264	289	273	283
Renal	274	305	331	349	378	410	417	425
Translational				191	222	244	249	264
Quality of Life					247	260	239	252
Imaging and Theranostics							44	68



Goal 3: Strengthen ANZUP's capacity for practice-changing clinical trials.

ANZUP continually refines its systems, procedures, and governance to effectively deliver its strategic plan. The Board of Directors oversees corporate governance, financial management, reporting, compliance, and organizational policy, ensuring a robust quality management system.

ANZUP has streamlined its IGWs using templates and regularly consults with subcommittees and members to identify opportunities for improved tools and collaboration.

As ANZUP's studies and membership grow, we recognise the importance of clearly defined decision-making processes and role allocations. Documented processes and policies support the quality and integrity of ANZUP operations, ensuring efficient execution of our strategic objectives.

Fundraising is crucial to ANZUP's sustainability. A diversified fundraising plan prioritises cost-effective initiatives. The Below the Belt Research Fund, supported by events and campaigns like 111 Your Way, the Below the Belt Pedalthon, Rude Food Cookbook, and the Sydney Sock Project, has raised over \$2.06 million to date, significantly contributing to ANZUP research.

31
DAYS

231
CHALLENGERS

20
TEAMS

580 HOURS
OF WORKOUTS AND
MEDITATION

21,000 KM
WALKED, RAN AND CYCLED

1,112 LAPS
SWAM

\$17,000+
RAISED FOR
BELOW THE BELT
CANCER RESEARCH

**Thank
You**
TO EVERYONE
WHO SUPPORTED
111 YOUR WAY!

THANKS TO OUR INCREDIBLE COMMUNITY, THE 111 YOUR WAY EVENT RAISED OVER \$17,000.

SYDNEY
Sock Project

ANZUP
Cancer Trials Group Limited

**Over \$15,000
raised!**



ANZUP'S COLLABORATION WITH THE SYDNEY SOCK PROJECT HAS SEEN OVER \$15,000 RAISED IN DONATIONS.



THE 2024 MELBOURNE PEDALTHON RAISED OVER \$43,000.

The ASM also contributes to ANZUP's financial health. The 2024 Gold Coast ASM, featuring a high-quality scientific program, attracted a record 485 delegates, showcasing ANZUP's research activities.

ANZUP 2024 ASM, GOLD COAST	2016	2017	2018	2019	2020	2021	2022	2023	2024
Delegates	297	335	390	392	320	404	399	446	485
International speakers	4	6	7	5	9	8	7	8	6
Submitted abstracts	57	78	53	73	49	54	56	81	77
Fellowships, scholarships and awards	40	47	42	39	43	44	36	55	104



Goal 4: Forward plan to maintain a vibrant and active urogenital cancer trials community.

In 2024/25, ANZUP continued to prioritise building and strengthening relationships with a diverse range of stakeholders. The Australian Government's funding through Cancer Australia remains crucial for supporting ANZUP's infrastructure. Cultivating relationships with donors, volunteers, philanthropists, corporate partners, and other key stakeholders remains a central focus, particularly within the Partnerships and Engagement portfolio.

Collaborative partnerships are essential to ANZUP's success. This year, ANZUP engaged in trials with other Cancer Cooperative Trials Groups (CCTGs) and actively participated in the Executive Officers Network (EON) and Clinical Trials Consumer Network (CTCN), facilitating information sharing among the CAP and strengthening inter-group collaboration.

ANZUP's key research collaborations in 2024/25 included partnerships with the NHMRC Clinical Trials Centre (CTC) at the University of Sydney (12 trials), the Centre for Biostatistics and Clinical Trials (BaCT) (3 trials), the Walter and Eliza Hall Institute of Medical Research (WEHI) (1 trial), the Hunter Medical Research Institute (HMRI) (1 trial), and The George Institute for Global Health (TGI) (2 trials). These partnerships ensure robust trial development and operations. Co-badged trials were also conducted with TROG, A/Prof Ben Tran, and the Peter MacCallum Cancer Centre (1 trial each).

ANZUP maintains strong relationships with key national organisations, including:

- Australia & New Zealand Urological Nurses Society (ANZUNS) – represented on the ANZUP SAC by Kath Schubach
- Australian Clinical Trials Alliance (ACTA)
- Cancer Australia
- Cancer Councils
- Clinical Oncology Society of Australia (COSA)
- Colleges (e.g. RACP, RANZCR, RACS)
- Medical Oncology Group of Australia
- Movember
- Prostate Cancer Foundation Australia (PCFA)
- TROG (Trans Tasman Radiation Oncology Group) Cancer Research
- Other National Cancer Cooperative Trials Groups
- Urological Society of Australia & New Zealand (USANZ)
- Walter and Eliza Hall Institute of Medical Research (WEHI)

International partnerships and collaborations continue with organisations such as:

- Alliance for Clinical Trials in Oncology
- Canadian Cancer Trials Group (CCTG)
- Cancer Research UK
- Cancer Trials Ireland (CTI)
- Children's Oncology Group (COG)
- Dana-Farber Cancer Institute
- European Organisation for Research and Treatment of Cancer (EORTC)
- Medical Research Council (MRC) UK
- National Cancer Institute
- Prostate Cancer Clinical Trials Consortium (PCCTC)
- Prostate Cancer Foundation New Zealand (PCFNZ)

ANZUP's multidisciplinary membership is its most valuable asset. In 2024/25, members benefited from a full calendar of educational and networking opportunities, including IGWs, the ASM, the Bladder and Prostate Masterclass, Best of GU Oncology Evening Symposium, educational workshops and events, and access to grant opportunities, scholarships, fellowships, and awards. These initiatives support fellows, trainees, and junior researchers, connecting them with experts to develop skills, enhance knowledge, critically evaluate research, and actively participate in trial development.



CONGRATULATIONS TO THE RECIPIENTS OF THE STUDY COORDINATOR SCHOLARSHIPS, AWARDED AT THE #ANZUP24 ASM.

A strengthened relationship with PCFA continues to improve access to and funding for prostate cancer trials. In a landmark announcement at the Parliamentary Big Aussie Barbie in Canberra on 10 October, 2024, PCFA and ANZUP formalised a three-year research partnership. This collaboration aims to accelerate clinical trials and advance prostate cancer treatment. The announcement was attended by prominent figures including Deputy Prime Minister The Hon. Richard Marles MP, Minister for Health The Hon. Mark Butler MP, Minister for Education The Hon. Jason Clare MP, and Opposition Leader The Hon. Peter Dutton MP.

Regular email, print, and social media updates are distributed to ANZUP members, keeping them abreast of the latest developments in GU clinical trials research, networking opportunities, and educational sessions. ANZUP membership provides individuals with a valuable connection to the GU cancer research community.



Goal 5: Provide leadership in collaborative cancer clinical trials

ANZUP's membership continues to grow and diversify, prompting ongoing evaluation of how best to support our multidisciplinary members and provide relevant opportunities. For the 2024/25 reporting period, we focused on tailored communication strategies to meet member needs. These included updates on trial development and management, trial news, and information on educational and fundraising events, disseminated through print, email, and social media channels. Member engagement in subcommittees also remains a key communication strategy.

ANZUP provides leadership and support to members through dedicated IGWs for each major cancer type we represent. Led by subcommittee chairs, these workshops offer educational and mentoring opportunities across our four tumour streams, as well as in quality of life, supportive care, imaging and theranostics, and translational research.

ANZUP maintains an active presence on X (Twitter), BlueSky, Facebook, Instagram, LinkedIn, and YouTube. Our online community has grown to nearly 9,000 followers across these platforms.

Nearly
9,000
followers



Funding, Fundraising & Philanthropy: A new and professional path into the future

The year 2024 marked a significant transition with the appointment of Adj. Prof Samantha Oakes as our new Chief Executive Officer. Her visionary leadership, combined with the strategic acumen of Marcel Svatos, our Business & Philanthropy Manager, has set a dynamic tone for our fundraising and philanthropy efforts. Their combined expertise is pivotal as we navigate towards our new strategic objectives.

Strategic Direction for 2025 and Beyond

End of 2024, ANZUP developed a comprehensive 5-year Fundraising and Philanthropy Strategy, which we will begin to implement in 2025. This strategy aligns with our forthcoming corporate Strategy and includes:

- **Innovative Fundraising Techniques:** We aim to explore new and innovative methods with our digital fundraising campaigns and leveraging social media platforms for broader reach.
- **Relationship Building:** Our primary goal is to deepen existing relationships and forge new ones with philanthropists, corporations, and other giving entities, emphasising sustainability and growth.
- **Long-Term Vision:** The 5-year plan ensures that our funding efforts are not just sustainable but will also allow ANZUP to fund more independent and investigator-led cancer research.

Engagement and Communication

Our approach to engagement includes:

- **Regular Interaction with Stakeholders:** We continue to nurture and expand our connections with philanthropists and other giving vehicles as well as intermediaries through consistent dialogue, ensuring they are well-informed about our activities and impact.
- **Customer Relationship Management (CRM) Database:** Significant resources will be allocated to a robust CRM that will facilitate our communication strategy, providing personalised, relevant and timely engagement with our stakeholders.
- **Enhanced Media Engagement:** By fostering relationships with key medical journalists and broadcasters, we will significantly increase media coverage of ANZUP's clinical trials and research, amplifying our reach and impact.

Looking Ahead

As we move forward with the implementation of our 3-year strategy in 2025, ANZUP will continue to:

- **Expand Our Network:** By engaging more deeply with new and existing partners, we aim to broaden our support base.
- **Innovate:** Experiment with new funding models and professionalise digital transformation in our fundraising strategies.
- **Measure Impact:** Establish clearer metrics for evaluating the effectiveness of our fundraising strategies and their alignment with our mission.

Research Highlights

Making waves globally

Scientific Advisory Committee: Ian Davis and Scott Williams



CHAIR, IAN DAVIS



DEPUTY CHAIR, SCOTT WILLIAMS

The ANZUP Scientific Advisory Committee (SAC) brings together a diverse array of medical and scientific disciplines, together with community representation. This immensely valuable body of expertise ensures that ANZUP is able to receive scientific and strategic guidance from a wide range of perspectives and experience. The SAC considers proposals from within ANZUP, coming through its various subcommittees and initiatives such as the Ideas Generation Workshops. It also reviews proposals coming from externally, including other cooperative groups, and provides guidance when ANZUP is asked to comment upon or endorse position papers or other similar documents. The SAC provides advice on how to prioritise when there are various projects competing for ANZUP resources. SAC members are involved in review and ranking of applications for ANZUP grants and fellowships, and provision of advice to the Board for use of discretionary funding.



ABOVE: ANOTHER PRODUCTIVE IDEAS GENERATION WORKSHOP - THIS TIME KIDNEY CANCER.

RIGHT: RECIPIENTS OF THE 2024 BELOW THE BELT RESEARCH GRANTS.



SAC has four disease-specific subcommittees: Prostate, Renal, Germ Cell, and Bladder / Urothelial / Penile. There are also three non-disease-specific subcommittees: Quality of Life and Supportive Care, Translational Research, and Imaging and Theranostics.

SAC membership includes a range of relevant medical disciplines, nursing, quality of life expertise, statistics, basic science, translational research, epidemiology, and consumer representation. New Zealand is specifically represented, as well as other international members, chairs and deputy chairs of the various subcommittees, and with representation ex officio of the ANZUP secretariat and deputy committee chairs. Trial principal investigators are also invited to attend. The SAC membership is reviewed annually by the Board.

The SAC executive comprises the ANZUP Board chair, Board deputy chair, SAC chair, subcommittee and Consumer Advisory panel chairs, ANZUP CEO, and ANZUP clinical trials project manager. This smaller but still representative group is occasionally called upon to provide rapid review and responses to time-critical opportunities or other issues. This ability to be agile while also consultative and inclusive is a defining characteristic of how ANZUP works.

The SAC meets three times per year virtually, and runs an extended face to face meeting at the Annual Scientific Meeting. The agenda has some standing items to review current activity, but the Committee aims to spend most of each meeting discussing strategic matters. Four hours for our face to face meeting is often not enough once the conversation starts to flow freely. The SAC recognises the realities of the clinical and research environment in which we work, but also has the intellectual freedom to visualise a desired future state and to plan how to achieve it. This has been pivotal to ANZUP's ability to design and conduct trials that may run over several years and still be profoundly relevant and impactful upon completion.

ANZUP is conscious that only a small minority of its members actively participate in its committees and related activities. All members are welcome to participate at whatever level suits them, and we are grateful to all of you for what you contribute. Your preferred level of involvement might be simply being kept aware through mailing lists and other communications; through to active participation in our various initiatives and taking on leadership roles. We want to provide opportunities wherever possible and would be glad to speak further with anyone interested. Please let the ANZUP team know if you wish to be added to any committee or other activity.

Ian Davis
Chair, ANZUP Scientific Advisory Committee

Bladder, Urothelial and Penile Cancer (BUP) Subcommittee

Dickon Hayne and Andrew Weickhardt



CHAIR, DICKON HAYNE

DEPUTY CHAIR, ANDREW WEICKHARDT

Bladder cancer starts in the bladder, the organ that holds urine, and is a relatively common cancer affecting around 5,000 Australian and New Zealand people every year. Urothelial cancer is the most common type of bladder cancer that begins in the lining of the urinary tract – and involves the bladder, as well as the tubes that connect the kidneys to the bladder (ureters), and the part of the kidney that collects urine. While we have seen improvements in the relative survival rate of other cancers thanks to life-improving research, the same is not true for bladder cancer; with only 57% of people affected by bladder cancer expected to meet their five-year milestone. Therefore, new therapeutic strategies for bladder cancer are desperately needed. Penile cancer is a rare cancer affecting only around 200 Australian and New Zealand people every year, and starts in the skin or tissue of the penis. Around 72% of people diagnosed with penile cancer will survive 5 years after their diagnosis^{1,2}. More research is needed to advance the outcomes of those affected bladder, urothelial, and penile cancers and ANZUP is pleased to report the following key achievements.

PCR-MIB A new combination treatment approach for people affected by muscle invasive bladder cancer.

Pembrolizumab is a type of immunotherapy that targets a marker on immune cells, called PD-1, and ‘takes the brakes off’ the immune system allowing the body’s immune system to recognise and attack cancer cells. Pembrolizumab can be used to treat locally advanced bladder cancer (cancers that have spread to nearby tissues) and metastatic bladder cancer (cancers that have spread out of the bladder wall and to other organs) effectively. There is some evidence that pembrolizumab can be added to either chemotherapy or radiation to improve tumour responses in people affected by metastatic bladder cancer, however the combination of

all three treatments has not yet been tested. ANZUP’s PCR-MIB trial tested whether the combination of pembrolizumab together with chemotherapy and radiation was safe and effective. In results published in the prestigious European Association of Urology journal in 2024, the combination treatment proved feasible with 88% of participants with bladder cancer experiencing a complete response to treatment after 24 weeks and 78% of participants free of spread to distant organs at 2 years. The results of this trial warrant further research to explore the clinical benefits of this combination in larger trials to prove that this combination approach is better than other standard of care treatment strategies.

G-DISCO: An Innovation in the Treatment for High-Risk Non-Muscle Invasive Bladder Cancer.

BCG (Bacillus Calmette-Guérin) is a treatment that helps stimulate the immune system within the bladder to fight and prevent recurrence or progression of bladder cancer. It is an effective treatment for intermediate and high-risk non-muscle invasive bladder cancer to delay the cancer progressing to a more advanced stage and decrease the need for radical surgical removal of the bladder later. Unfortunately, despite the efficacy of this treatment, some people are unsuitable or do not respond to this treatment and others may decline removal of the bladder to lower the risk of the cancer returning. For people with this disease, a combination chemotherapy approach (first gemcitabine and then docetaxel) injected into the bladder is often recommended, to reduce the risk of the cancer returning. These two chemotherapies are administered sequentially, requiring two-hour dwell times for each drug (the time the chemotherapy is in the bladder), resulting in significant time demands (~5 hours) for patients and strains on healthcare resources. G-DISCO represents a first-in-human trial of synchronous administration of gemcitabine and docetaxel into the bladder. By combining both agents, this trial explores a novel strategy aimed at reducing procedural burden (reducing the time the patient is being treated) and health care costs while maintaining efficacy. The G-DISCO study has progressed remarkably, moving from initial discussion at the Idea Generation Workshop to trial opening in just 10 months. The first patient has already been recruited and received their first dose in January. The G-DISCO team also presented

1. Cancer Data in Australia, Australian Institute of Health and Welfare (AIHW) 2024

2. New Zealand Cancer Registry (NZCR), Health New Zealand-Te Whatu Ora



ANZUP'S G-DISCO POSTER SHOWCASED AT ASCO GU 2025 BY DR KEVIN KEANE.

a poster at the American Society of Clinical Oncology Genitourinary Symposium in San Francisco in February, further highlighting the study's momentum and growing global recognition. This rapid progress underscores the subcommittee's efficiency and focus on translating research into patient benefit. This ANZUP-led trial was funded by a Below the Belt grant through the generosity of the ANZUP community and has the potential to be practice-changing and represents a major step forward in bladder cancer research.

SUBDUE-1: World-first trial of an innovative bladder cancer delivery method showing promise.

A world-first SUBDUE-1 trial has explored an innovative strategy for treating bladder cancer. Instead of delivering the immunotherapy drug (durvalumab) through a vein or into the bladder itself (intravesicle), the immunotherapy is injected directly into the bladder tissue; the location where bladder cancers develop, with the aim of maximising the effects of the drug directly to cancer cells. By doing so, this delivery method could potentially alleviate immune related side effects caused by immunotherapy delivered throughout the body via the vein.

Eleven patients have been recruited that were planned for bladder removal (cystectomy), and the initial results were promising: following durvalumab injection and removal of the bladder, there was an increase in immune cells in the bladder wall, suggesting immune system activation that could potentially work to fight the cancer. The new injection method was also shown to be feasible and safe paving the way for more studies that investigate whether this innovative treatment strategy can improve overall survival and quality of life for those affected by advanced and metastatic bladder cancer. The results of the SUBDUE-1 trial were published in the prestigious British Journal of Urology International (BJUI) in August 2024.

Australian Penile Cancer Registry: Increasing the understanding of a rare cancer to reduce the burden and improve outcomes of those affected by penile cancer.

Penile cancer is a rare disease that affects approximately 1 in 100,000 people in Western countries. Despite its rarity, penile cancer can have a significant impact on patients' quality of life and is associated with high rates of morbidity and mortality. Currently, largely due to the disease's rarity, there is a lack of comprehensive data on the risk factors and management of penile cancer in Australia and to address this gap in knowledge, thanks to funding in part through the ANZUP Below the Belt research fund, the Australian Penile Cancer Registry is being developed.

The aim is to establish a database that can document local risk factors, assess the effectiveness of current management of penile cancer and to improve the understanding of penile cancer, including its underlying biology and patterns of disease. By evaluating the effectiveness of current treatments, it is hoped that the information collected will facilitate further research to identify better ways of managing and treating penile cancer with the potential to inform clinical practice and improve patient outcomes.

Last year, the database infrastructure was established and data collection has begun, which will expand across Victoria and New South Wales, with plans to onboard new sites nationwide over the next 6–12 months. International collaboration is also on the horizon. Engagement with the Danish Penile Cancer Registry (1,800 cases over 20 years) has already begun, with work underway on a plan to integrate data from multiple registries is underway. This will enable future capacity to link and compare Australian, English, and Danish presentation, demographics, treatments, outcomes, etc.

The establishment of an Australian Penile Cancer Registry that will build knowledge in this rare cancer type has the potential to make a significant contribution to the field of penile cancer research, informing and improve outcomes for people affected by penile cancer.

Renal Cell Subcommittee

Craig Gedye and David Pook

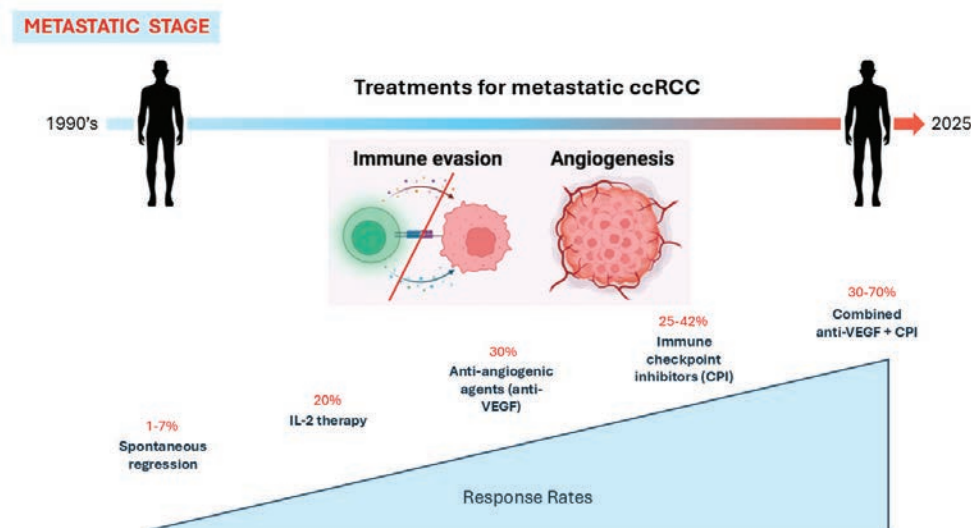


CHAIR, CRAIG GEDYE



DEPUTY CHAIR, DAVID POOK

Renal cell cancer is a disease that begins in the kidneys. Imagine your kidneys as two sophisticated cleaning systems in your body, constantly filtering your blood to remove waste and make urine. Renal cell cancer is what happens when some of the normal cells in your kidney start to grow uncontrollably, forming a lump or tumour. Kidney cancer affects over 5,000 people in Australia and New Zealand every year and while progress has been made over the last 30 years with the emergence of targeted treatments and immunotherapy for kidney cancer, only around 70% expected to survive 5 years after their diagnosis^{1,2}.



ABOVE: A 30-year perspective on response rate improvements in kidney cancer – presented by Dr Lewis Au. Thanks to world class research, new therapies for kidney cancer are now available (including targeted and immunotherapies) resulting in a 40% improvement in the mortality rate of kidney cancer over the last 30 years – but more research is needed to improve survival rates.

The renal cell committee is pleased to report the following milestones:

KEYPAD: A new combination therapy with a drug that is used in the treatment of osteoporosis with immunotherapy to fight kidney cancer.

Kidney cancer (or renal cell carcinoma) is 7th most diagnosed cancer in Australia. Approximately 80% of kidney cancers are classified as clear cell renal cell carcinomas and around 20% are the rarer subtype of non-clear cell carcinomas. While there are differences in the way these cancers behave, the five-year relative survival rate for Australians diagnosed with kidney cancer is 82.3%. Immunotherapies, that help the body fight the cancer, have been shown to be effective in about a quarter of patients with clear cell renal cell carcinoma after standard of care treatment has failed.

Denosumab, sold under the brand name Prolia, is an antibody used to control bone loss in people with osteoporosis but has also been used in advanced cancer to strengthen bones and reduce the risk of fractures for people with cancer. Denosumab is also believed to modify the behaviour of the immune system, an effect which has stimulated the interest in the use of this drug in combination with immunotherapies.

The ANZUP KEYPAD study tested whether denosumab can team up with immunotherapy (pembrolizumab) to shrink tumours and improve survival for people diagnosed with clear cell kidney cancer. The trial recently hit a major milestone, the completion of the trial and preparation of study results, bringing it one step closer to potentially changing treatment guidelines. Initial findings indicate that the combination of the two

treatments is safe with early indications of response in some patients with final results due to be published in the coming year.

The Renal Cell Subcommittee also developed the Outcome of Kidney Cancer Project in collaboration with the Quality of Life (QoL) Subcommittee. For more details, please refer to the QoL Report.

1. Cancer Data in Australia, Australian Institute of Health and Welfare (AIHW) 2024
2. New Zealand Cancer Registry (NZCR), Health New Zealand-Te Whatu Ora

Prostate Subcommittee

Lisa Horvath and Jarad Martin



CHAIR, LISA HORVATH



DEPUTY CHAIR, JARAD MARTIN

Prostate cancer remains the most commonly diagnosed cancer in Australia and New Zealand with over 30,000 people expected to be diagnosed every year. Thanks to world class research, prostate cancer can be treated effectively for the majority of the people affected^{1,2}. Nevertheless, over 4,000 people every year will die due to an advanced or hard-to-treat form of prostate cancer and many more people will have life-long treatment related side-effects including morbidity associated with long-term hormonal suppression, sexual dysfunction and mental health issues³. The Prostate Cancer Subcommittee delivered an exceptionally productive year, marked by significant advancements in research and patient care. Our activities spanned the spectrum from pioneering research to rapid trial activation, reflecting a multidisciplinary and patient-focused approach.

#UpFrontPSMA: The first study of its kind to show a clear benefit of the radioligand therapy LuPSMA followed by chemotherapy in advanced hormone sensitive prostate cancer.

Most prostate cancer cells have a marker on their surface called prostate cancer specific membrane antigen (PSMA), that can be used in imaging to identify where prostate cells have spread throughout the body. PSMA positive prostate cancer cells can also be targeted a type of radionuclide therapy called Lutetium-177 PSMA (LuPSMA). LuPSMA is a treatment that can find prostate cancer cells anywhere in the body and deliver a dose of radiation to kill them. The emitted radiation only travels about 1mm, which means it mainly causes the death of cancer cells, while avoiding healthy cells, and is well tolerated with few side effects. LuPSMA has been shown to be effective improving survival and quality of life in people affected by metastatic prostate cancer who have no other treatment option options.



EXCITING RESULTS FROM THE #UPFRONTPSMA STUDY PRESENTED AT ESMO 2024 IN BARCELONA BY PROF MICHAEL HOFMAN AND PROF ARUN AZAD.

UpFront PSMA tested whether LuPSMA therapy is an effective treatment in patients that have newly diagnosed advanced (metastatic) prostate cancer. The standard of care treatment for these patients is androgen deprivation therapy (a hormonal treatment that reduces testosterone levels in the body, starving prostate cancers of their fuel) followed by chemotherapy (docetaxel). This trial examined whether adding LuPSMA to chemotherapy was better than docetaxel chemotherapy after all patients received androgen deprivation therapy (standard of care). Professor Arun Azad presented the results of the #UpFrontPSMA trial at the European Society of Clinical Oncology in Barcelona, with simultaneous publication in The Lancet Oncology and the results showed that at 48 months, a larger proportion of participants (41%) who received LuPSMA in addition to standard-of-care had undetectable levels of prostate serum antigen (PSA) in the blood stream compared to only 16% of participants in the standard-of-care only arm. Side effects of the treatments were similar in both arms suggesting that the addition of LuPSMA did not worsen chemotherapy-related side effects. While larger trials are needed, this trial indicated that the addition of LuPSMA to standard of care is a promising option to control disease in people affected by newly diagnosed advanced prostate cancer.

Landmark ENZA-p Study: A new combination treatment approach improves overall survival and quality of life for people diagnosed with high-risk hard-to-treat advanced (metastatic) prostate cancer

Around 96%¹ of people diagnosed with prostate cancer will survive to their five-year milestone but for those with advanced (metastatic) and hard-to-treat cancer, this number is much lower at around 40%³. Better treatments for advanced and hard-to-treat prostate cancers are desperately needed. While hormone treatments like enzalutamide, which block the effects of testosterone, can slow cancer growth in people with advanced prostate cancer, unfortunately, some people will develop resistance to the treatment and around 1 in 4 people will never respond.

The world first ENZA-p study, led by Professor Louise Emmett, tested whether a powerful new combination of LuPSMA combined with enzalutamide could improve outcomes in people diagnosed with high-risk advanced (metastatic) castration-resistant prostate cancer. The trial also tested an innovative world-first treatment approach called 'adaptive dosing,' which uses imaging and blood results to identify patients who are responding to the treatment and determine those patients who were most likely to benefit from continued treatment, tailoring the treatment approach for each patient.

The primary study results were published in The Lancet Oncology in 2024, with further followup and secondary endpoints published in The Lancet Oncology in early 2025. The findings showed that the new combination increased the time it took for the cancer to get worse, thereby improving overall survival and quality of life. Patients lived longer and better on the combination treatment. The study opens the door for exploring this combination earlier in metastatic prostate cancer and garnered significant media attention, across national media and including a page 3 piece in The Australian and was presented at the American Society of Clinical Oncology Genitourinary Symposium in San Francisco in 2024. For more information, please visit our website at <https://bit.ly/enza-p>.

POSITIVE OVERALL SURVIVAL AND QOL OUTCOMES FROM THE ENZA-p STUDY PRESENTED BY PROF LOUISE EMMETT AT ASCO GU 2025.



WOMBAT: A new approach to outsmart treatment-resistant prostate cancer

Prostate cancer cells rely on testosterone for their survival and growth. Androgen deprivation therapy reduces testosterone levels in the body starving prostate cancers of their fuel and are highly effective treatments to control the growth of prostate cancer. Androgen deprivation therapy can be used in combination with androgen receptor pathway inhibitors, which act to suppress the action of testosterone on prostate cancer cells, is a two-punch attack to limit the growth of prostate cancer cells resulting in improved outcomes for people affected by prostate cancer. While effective, these hormonal treatments used over long periods of time can be associated with unwanted effects like hot flashes and night sweats, and treatment resistance will eventually develop. This often shows up as an increase in prostate-specific antigen (PSA), measured through a blood test.

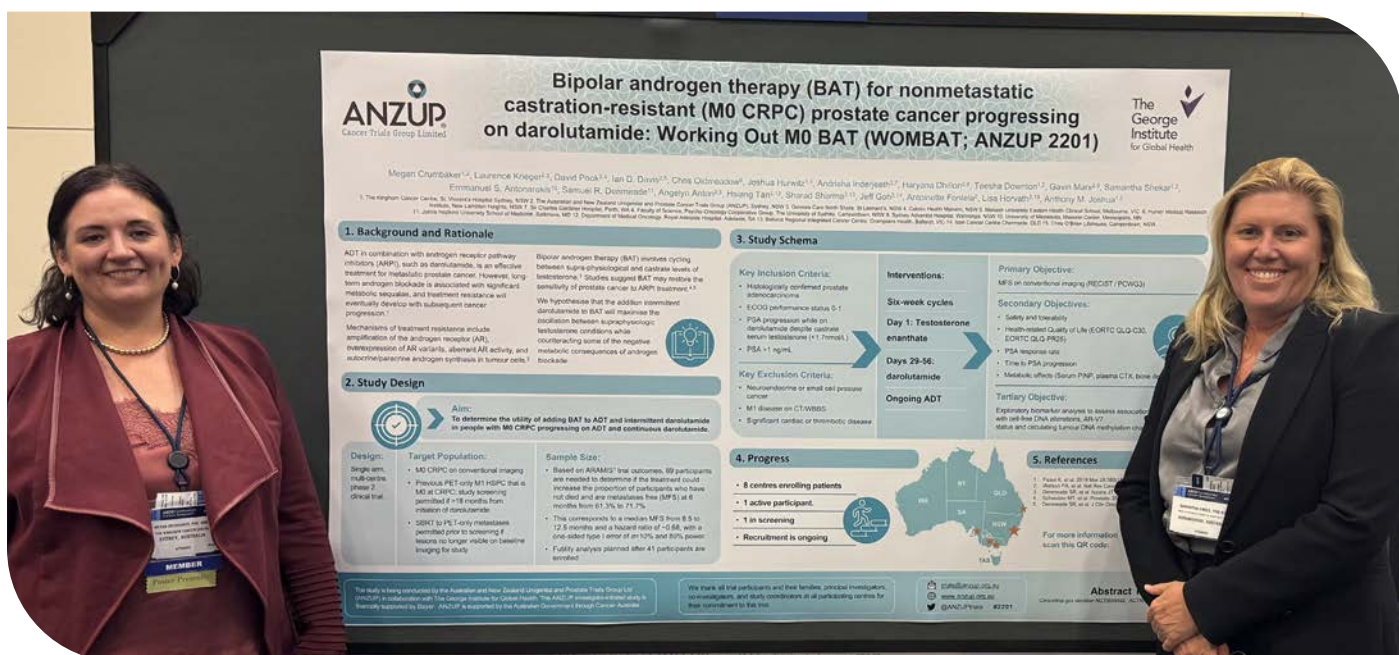
In an attempt to combat prostate cancer treatment resistance, an innovative treatment called bipolar androgen therapy (BAT) has been developed, which involves cycling between very-high levels and very low levels of testosterone. WOMBAT is designed to test whether the addition intermittent androgen receptor pathway inhibition (darolutamide) to BAT that cycles between high and low levels of testosterone can restore the sensitivity of prostate cancer to hormonal treatment while counteracting some of the negative metabolic consequences of long-term hormonal therapy.

The WOMBAT trial is progressing rapidly. Recruitment commenced in August 2024, the first patient was enrolled in January 2025, and the progress of the trial was presented at the American Society of Clinical Oncology Genitourinary symposium in February 2025. This progress highlights the Subcommittee's efficiency and dedication to bringing promising therapies to patients.

THE ENZA-p STUDY CAPTURES MEDIA SPOTLIGHT, FEATURED PROMINENTLY IN THE AUSTRALIAN.



1. Cancer Data in Australia, Australian Institute of Health and Welfare (AIHW) 2024
2. New Zealand Cancer Registry (NZCR), Health New Zealand-Te Whatu Ora
3. National Cancer Control Indicators; relative survival for prostate cancer by stage, 2011



AT ASCO GU 2025, DR MEGAN CRUMBAKER PRESENTED THE WOMBAT STUDY POSTER ALONGSIDE ANZUP CEO ADJ PROF SAMANTHA OAKES.

GenI-AIRSPACE: Personalising prostate cancer care through genetic testing

Prostate cancer affects over 30,000 people in Australia and New Zealand each year, but not all cases are the same. Some grow slowly and may never need aggressive treatment, while others can progress quickly. Currently, doctors rely on several diagnostic tools and biomarkers (eg. prostate serum antigen (PSA) levels in the blood, imaging, biopsy pathology, tumour burden cancer) to decide whether a patient should undergo active surveillance (monitoring without immediate treatment) or receive other treatments. However, these methods aren't perfect and are poor predictors outcome. This dilemma inevitably leads to overtreatment of large numbers of low-risk cases with expensive treatments that often have unwanted side effects. A better way to personalise care could help people avoid unnecessary procedures while ensuring those at higher risk get timely treatment.

The GenI-AIRSPACE trial, activated in November 2024, aims to determine if genetic testing can refine treatment decisions for people with favourable intermediate risk prostate cancer. The trial will use three different, but complimentary types of genetic tests and aim to produce 'genetic risk scores' that can safely guide clinical management. These tests may identify those people who have an elevated risk of the cancer getting worse and requiring immediate treatment from those with low-risk prostate cancers that can go on active surveillance and can be safely spared active treatment.

This trial could transform prostate cancer management and provide evidence for the implementation of genetic testing as a routine part of prostate cancer care. The future of prostate cancer care can be smarter, safer, and more personalised. GenI-AIRSPACE is leading the way.

1. Cancer Data in Australia, Australian Institute of Health and Welfare (AIHW) 2024
2. New Zealand Cancer Registry (NZCR), Health New Zealand-Te Whatu Ora
3. National Cancer Control Indicators; relative survival for prostate cancer by stage, 2011

Germ Cell Cancer Subcommittee

Ben Tran and Ciara Conduit



CHAIR, BEN TRAN



DEPUTY CHAIR, CIARA CONDUIT

Germ cell cancers are uncommon, affecting just over 1,000 people every year in Australia and New Zealand every year, but these cancers have a high burden on the lives of young people^{1,2}. Research focused on understanding these tumours is crucial for improved diagnosis, treatment and better quality of life. The Germ Cell Subcommittee has continued to make strides in research and clinical trials, demonstrating its commitment to advancing the field. Key highlights from this year include:

Hope for fewer unnecessary treatments: The CLIMATE trial nearing completion with results expected to advance cancer care.

Most people diagnosed with testicular cancer will have cancer confined to the testicle, without evidence of spread to other areas of the body. These people are highly likely to fully recover following surgical removal of the testicle (orchidectomy) alone, and most will not require additional chemotherapy or radiotherapy. Sometimes, a person may choose to undergo preventive chemotherapy or radiotherapy, which reduces the risk of their cancer coming back; however, this may result in long-term side effects for some people. For this reason, most people in Australia are recommended active surveillance, which involves regular reviews with their doctor, computerised tomography (CT) scans and blood tests, but no chemotherapy or radiotherapy. With this approach, most people will be spared from unnecessary treatment and side effects. However, in a small number of these people, the cancer will return (recurrent cancer). Reassuringly, these people are also highly likely to have a positive outcome following additional treatment.

The CLIMATE trial is investigating a new blood test, that tests the presence of a small marker, or molecule, called miRNA-371 (a micro-ribonucleic acid) that can reliably predict the presence of a cancer. Preliminary studies have found that miRNA-371 is detectable in blood samples of people who have known testicular cancer. The CLIMATE trial will examine whether the presence of miRNA-371 in the

blood after orchidectomy (removal of the testis) can predict outcomes for those affected. The trial will examine whether the presence of miRNA-371 (positive predictive value) can predict the return of the cancer (relapse) within 12 months and conversely whether the absence of the miRNA-371 in the blood can predict absence of disease (negative predictive value). If proven to be a reliable test, this would help clinicians determine those who can be spared from unnecessary treatment and side effects and those that may require more aggressive treatment.

Recruitment for the CLIMATE trial is nearing completion, with 178 out of 200 patients enrolled as of 31 March 2025. ANZUP recognises this as a significant milestone in a rare cancer type and the results of the study are expected to advance the management of people affected by testicular cancer.

iTestis: Over 2,500 participants enrolled in a registry that will advance the understanding of Germ Cell Tumours.

The iTestis platform, a user friendly, multidisciplinary, web-based Germ Cell Tumour database (testicular cancer and cancers that occur outside the testis), was established with funding from ANZUP's Below the Belt fund made possible with the generosity of the community. iTestis aims to collect current clinical information about patients who have been diagnosed and treated for Germ Cell Tumours in Australia. While testicular cancer is the most diagnosed cancer in young men, testicular cancer and other germ cell tumours are rare compared to other cancers, therefore enrolling enough participants onto clinical trials in Australian and New Zealand is difficult. For this reason, clinicians often look at large international studies to provide the best evidence for clinical management decisions. In 2024/2025, iTestis marks meeting the enrolment milestone of over 2,500 participants and data has been successfully utilised for research exploring cancers that originate outside of the testes (extragonadal primary) as well as studies exploring the responses to chemotherapy after orchidectomy (removal of the testis). iTestis has also been utilised as the clinical trial database for cohort studies CLIMATE, PRESTIGE and PREPARE, allowing clinical trials to be conducted more efficiently and involve real-world patients and has provided a valuable resource that will help expand the understanding of germ cell tumour development and treatment response.



A/PROF BEN TRAN AND DR CIARA CONDUIT LED THE GERM CELL IDEAS GENERATION WORKSHOP.

1. Cancer Data in Australia, Australian Institute of Health and Welfare (AIHW) 2024
2. New Zealand Cancer Registry (NZCR), Health New Zealand-Te Whatu Ora

Quality of Life and Supportive Care Subcommittee

Haryana Dhillon and Natasha Roberts



CHAIR, HARYANA DHILLON



DEPUTY CHAIR, NATASHA ROBERTS

ANZUP's members are part of disease-specific subcommittees which are responsible for the oversight of trials within their portfolios, as well as the development of new trial concepts. There are also non-disease-specific subcommittees, such as Quality of Life and Supportive Care, which form an integral part of trial development and management to maximise benefit for people with Below the Belt cancers. The Quality of Life and Supportive Care Subcommittee continued to strengthen partnerships with other ANZUP subcommittees, providing advice and assistance including the use of patient reported outcome measures across ANZUP's trial portfolio leading to a better understanding of improvements in quality of life for those affected by Below the Belt cancers.

Driving patient-centred research: Subcommittee integrates patient reported outcomes into clinical trials

Subcommittee members have contributed to the integration of patient-reported outcomes into several clinical trial proposals. Patient-reported outcomes are any direct reports of a patient's health status that come directly from the patient, without interpretation or amendment by others. They capture the patient's perspective on their health and well-being. Patient reported outcomes can be used to measure various aspects of a patient's experience, including symptoms, function, and quality of life.

Collaborative development of a cognitive bias modification trial for platinum-related tinnitus

In collaboration with the Germ Cell Subcommittee, a clinical trial of a cognitive bias modification intervention for tinnitus in people treated with platinum containing regimes has been developed. Many cancer survivors experience tinnitus as a long-term side effect of chemotherapy treatment that includes cisplatin and other platinum-based drugs. While many can cope well, tinnitus can become a major source of distress. Unfortunately, there is no known cure for tinnitus, and treatment is typically aimed at reducing distress. However,

established modes of treatment (i.e. psychological therapy) are often costly and time intensive, and many who suffer from tinnitus do not seek treatment. A previous study found that a brief, online intervention known as Cognitive Bias Modification for Interpretation (CBM-I) can help to alleviate the experience of pain in survivors of breast and ovarian cancer. Given the parallels between the cognitive processes underlying pain and tinnitus distress, this pilot study seeks to explore the feasibility and acceptability of using this approach in a group of cancer survivors suffering from tinnitus. It is hoped that this will inform the development of a new, low-cost intervention aimed at helping those with tinnitus more easily cope with this condition.

OAK Study: Advancing non-invasive kidney cancer care through patient-centred resources

There is very little evidence for the management of active surveillance for patients with kidney cancer. Recognising the unmet informational and supportive care needs highlighted by consumer-led research, OAK is developing an innovative digital resource to empower patients, families, and clinical teams in accessing non-invasive kidney cancer treatment options. The OAK project is actively progressing in collaboration with the Consumer Advisory Panel (CAP).

The OAK resource will provide:

- Clinical recommendations prioritizing consumer needs and equipping teams in Australia and New Zealand to provide non-invasive care.
- Informational resources tailored to patients and carers.
- Decision-making resources empowering consumers to actively participate in care decisions.



CAP MEMBERS JULIET DE NITTIS AND RAY ALLEN SHARED VALUABLE CONSUMER INSIGHTS AT THE #ANZUP24 ASM.

The Outcome for Australian Kidney Cancer Patients (OAK) study was highly recommended by the ANZUP Scientific Advisory Panel to receive discretionary funds, made possible by the generosity of the ANZUP community, which would not otherwise secure funding from other sources and is aimed at supporting research strongly aligned with ANZUP's mission.

Translational Research Subcommittee

Arun Azad and Anthony Joshua



CHAIR, ARUN AZAD



DEPUTY CHAIR, ANTHONY JOSHUA

Translational research bridges the gap between clinical and basic (laboratory) research and helps increase our understanding of cancer and leading to improvements in diagnosis, prognosis, prediction tools and clues into new treatments. Translational research applies findings from basic science to enhance human health and well-being. It implements a “bench-to-bedside” approach and back – from laboratory experiments through clinical trials and improvements in the clinical management of disease as well as harnessing data and samples from clinical trials to advance the understanding of disease.

Patients who participate in ANZUP trials are often asked to consent to the collection of blood and tissue samples which might be used to conduct translational research studies in Australia and/or overseas. At ANZUP, we have a strong translational focus because that the more that is learnt about urogenital cancer, the faster improvement can be made in the lives of people affected by bladder, kidney, testicular, penile and prostate cancers.

The Translational Research (TR) Subcommittee has been highly productive over the past year, with notable achievements in our TheraP and ENZAMET studies as well as opening our new prostate cancer study WOMBAT for recruitment.

TheraP translational research reveals a new blood-based biomarker for predicting response to treatment

For people with advanced prostate cancer that stops responding to hormonal treatment, chemotherapy (cabazitaxel) is often the next step. But it can cause fatigue, nausea, and other side effects. While chemotherapy can help, many people struggle with its toll on their quality of life.

The TheraP trial found that a targeted radiation therapy called Lutetium-177 PSMA (LuPSMA) increased the proportion of people affected by advanced prostate cancer who responded to treatment – and with a better quality of

life compared to chemotherapy (cabazitaxel). While similar outcomes in terms of survival were observed, these results suggested that LuPSMA is a promising treatment alternative to chemotherapy for people whose cancer has progressed. The next question was to determine whether a biomarker could be developed to better choose the right treatment for the right patient.

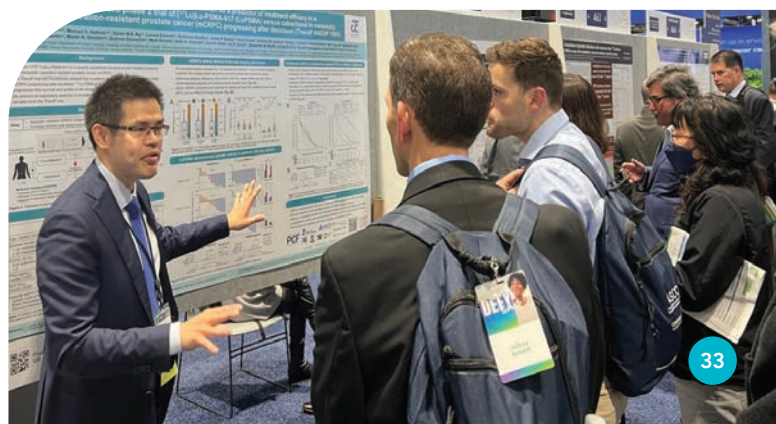
To address this question, Dr Ed Kwan looked to the DNA that leaks out of a tumour and is found in the blood, called circulating tumour DNA (ctDNA). This analysis, drawn from 290 blood samples across 180 men in TheraP found that ctDNA levels are predictive of tumour burden (how much tumour is present in the body), with lower ctDNA levels, a sign of less aggressive disease, indicative of better

response to LuPSMA therapy. In contrast, patients with higher ctDNA levels did not benefit as much from LuPSMA, though they may still respond to chemotherapy. The study also found that specific gene mutations (or spelling mistakes) in cancer ctDNA also revealed hidden vulnerabilities to targeted therapies, allowing a more tailored approach without needing invasive biopsies or outdated tissue samples. This is the first real-world evidence in prostate cancer that blood-based tumour DNA can guide which treatment is likely to work and potentially provide a simple test that could be accessible at sites across Australia and New Zealand. Unlike traditional methods that rely on biopsies or outdated tissue samples, Dr Kwan’s work also reveals that specific gene mutations in a patient’s ctDNA may indicate cancer vulnerability, bringing us closer to truly personalised care, offering a more contemporary and less invasive approach to treatment selection. The TheraP circulating tumour DNA (ctDNA) analysis was presented at The American Society of Clinical Oncology in June 2024 gaining significant interest in the global clinical research community.



DR EDMOND KWAN

DR EDMOND KWAN PRESENTED THE ANZUP THERAP TRIAL POSTER AT ASCO 2024.



ENZAMET: Life-extending treatment – translational work begins

When prostate cancer spreads, treatment becomes more challenging. Standard hormone therapy has been a mainstay, but over time, cancer can become resistant, leading to disease progression and shorter survival.

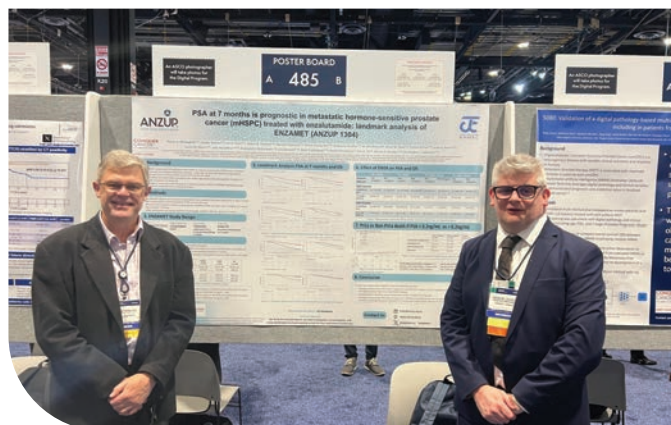
The globally significant large Phase III ENZAMET trial demonstrated that adding enzalutamide to standard hormone therapy can help people with metastatic hormone-sensitive prostate cancer live longer and delay disease progression, with manageable side effects. As a result of the practice changing ANZUP ENZAMET trial and others, enzalutamide (marketed as Xtandi) was added to Australia's Pharmaceutical Benefits Scheme (PBS) on August 1, 2023. This inclusion means that eligible patients can now access this life-extending treatment at a subsidized cost, reducing the financial burden significantly. Previously, patients might have faced costs up to \$44,000 per course; with PBS listing, the cost is approximately \$30 per prescription.

But the work doesn't stop there. Translational research using data and biological samples collected from the ENZAMET clinical trial is ongoing. There are currently 17 translational studies in progress as part of a global collaboration.

For example, chemical messengers (RNAs) carrying instructions from the DNA to proteins and other components in the cell are being examined in the tumour samples from the patients in the ENZAMET study. These assays are called gene expression profiling and help identify which genes or combinations of genes are active or inactive in cancer cells providing insights into how cancer cells grow, survive and resist treatment. This can help reveal vulnerabilities that could be exploited for future treatments. Gene expression profiling can also provide prognostic information, can predict response to treatment, can help provide risk stratification information and guide treatment decision.

In 2024, an ENZAMET translational research study published in the *Journal of Clinical Investigation* showed that patients who inherited a specific 'better outcome' version of the *HSD3B1* gene responded better to treatment, showing longer periods without the cancer getting worse and living longer when treated with drugs like enzalutamide, compared to those who didn't have this gene version. This study also provided a potential clue to how patients who have the 'poor outcome' version of *HSD3B1* could be potentially resensitised to treatment. Research like this increases the understanding of prostate cancer, how it responds to treatment and what vulnerabilities can be harnessed for new and improved treatment strategies.

Other translational research studies are investigating the potential of genomics (the information related to DNA including its genes), lipidomics (the presence of fat molecules in tumour and blood), proteomics (the profile of proteins in tumour and surrounding tissues), multiplex imaging (advanced imaging to study cancer cells), and AI-machine learning algorithms to further understand how prostate cancer develops, progresses, and responds to treatment- ultimately aiming to personalize care and improve outcomes for each patient.



THE ENZAMET TRIAL RECEIVED A MENTION DURING PROF CHRISTOPHER SWEENEY'S TALK AND PANEL DISCUSSION AT ACTA 2024.



ANZUP'S ENZAMET TRIAL WAS IN THE SPOTLIGHT AT ASCO 2024, WITH DR RONAN ANDREW MCLAUGHLIN PRESENTING THE POSTER ALONGSIDE ANZUP CHAIR PROF IAN DAVIS.

Imaging and Theranostics Subcommittee

Andrew Scott and Narjess Ayati



CHAIR, ANDREW SCOTT



DEPUTY CHAIR, NARJESS AYATI

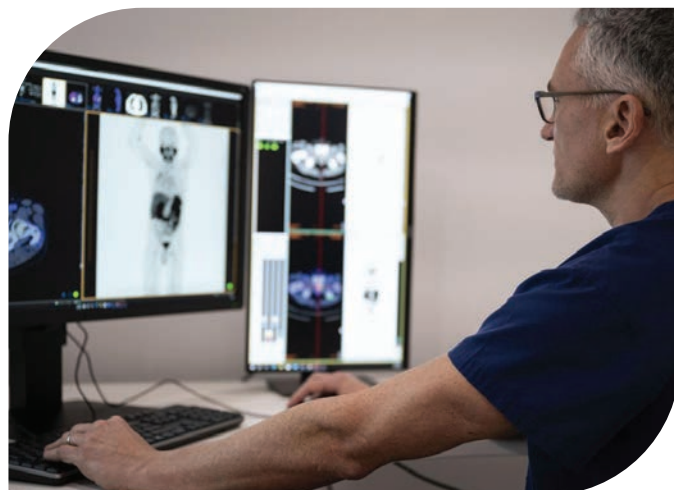
The Imaging and Theranostics Subcommittee focuses on advancing the field of molecular imaging and radionuclide therapy for the diagnosis and treatment of Below the Belt cancers having contributed impactful results last year and provide the following key highlights.

ENZA-p SPECT Imaging Analysis: Establishing feasibility for standardised LuPSMA Imaging

The subcommittee acknowledges the pivotal results of the ENZA-p study, published in The Lancet Oncology. Prof Louise Emmett, ENZA-p Study Chair and Director of American Society of Clinical Oncology Genitourinary symposium in 2025. The ENZA-p study demonstrates a world-first treatment combination that significantly improves survival and quality of life for people with advanced prostate cancer. This ground-breaking research has had a major impact on the field of prostate cancer management.



PROF LOUISE EMMETT (LEFT), LEAD INVESTIGATOR OF THE ENZA-p STUDY.



THE IMAGING AND THERANOSTICS SUBCOMMITTEE SUPPORTS SPECT IMAGING ANALYSIS FOR THE LANDMARK ENZAP STUDY.

The Imaging and Theranostics Subcommittee is proud to highlight that the associated SPECT imaging analysis that was used in the trial and was funded by the ANZUP Below the Belt Research Fund, successfully established the feasibility of standardising serial Lu-PSMA SPECT imaging across multiple sites in Australia. SPECT imaging, or Single Photon Emission Computed Tomography, is a nuclear medicine imaging technique that uses radioactive markers injected into the vein of a participant and viewed with sophisticated cameras to create three dimensional images of tissues, organs and cancer tissue. SPECT can be used in diagnosis, staging and monitoring of disease and can also be used track cancer that has spread to the bone. In ENZA-p, many participants had advanced prostate cancer that had spread to bone, therefore SPECT imaging was useful to diagnose and monitor participants in this trial. The establishment and credentialling of the SPECT infrastructure across multiple sites in Australia facilitated by this trial has now provided a key resource for future work requiring this imaging technique.

PSMA PET Machine Learning: Using AI to improve prostate cancer detection.

The subcommittee actively supports promising research initiatives, including PSMA PET Machine Learning (Dr. Son To/Prof. Chris Sweeney), which is pushing the boundaries of imaging technology in prostate cancer care.

The PSMA Machine Learning project is developing new computational tools to analyse PSMA PET studies, aiming to improve prostate cancer detection. Imaging plays a central role in the screening and detection of prostate cancer. Machine learning has the potential to assist radiologists detect and characterise clinically significant lesions, however this technique needs to be validated under real-world conditions to ensure accuracy, reliability, and safety. The researchers plan to use machine learning to aid the detection of bony metastases on PSMA PET-CT scans, as well as aid the grading of cancers on prostate MRI.

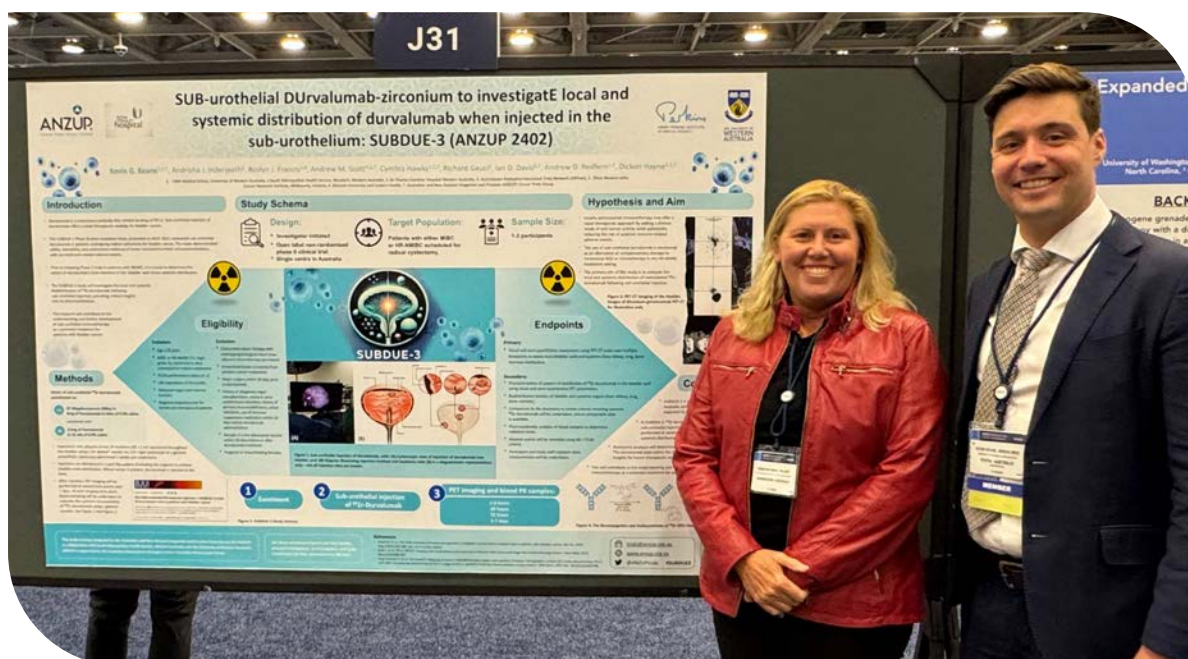
By bridging innovative machine learning techniques with frontline clinical imaging, this project holds the potential to transform how prostate cancer is detected and managed.

SUBDUE-3: Tracing immunotherapy to transform bladder cancer treatment.

The Subcommittee also supports the SUBDUE-3 Study (Prof Dickon Hayne/A/Prof Ros Francis)—an innovative bladder cancer clinical trial. This study is exploring how imaging can unlock new understanding of immunotherapy in bladder cancer treatment.

The SUBDUE-3 study is evaluating a highly novel treatment approach for patients with bladder cancer. SUBDUE-3 is designed to track where an immunotherapy (Durvalumab), that is used in the treatment of bladder cancer goes in the body when injected directly into the bladder wall. The researchers are investigating if the drug stays mostly in the bladder or if it spreads throughout the rest of the body producing unwanted body wide side effects. To do this, the investigators are using a special version of Durvalumab that's tagged with a radioactive substance called Zirconium. This allows to track the drug's movement using special scans (PET and SPECT scans) after it's injected.

By combining targeted immunotherapy with advanced imaging, the SUBDUE-3 study is helping redefine how and where bladder cancer treatments work.



ANZUP'S BLADDER CANCER TRIAL SUBDUE-3, LED BY PROF DICKON HAYNE, WAS PRESENTED BY DR KEVIN KEANE AT ASCO GU 2025.

ANZUP's Ideas Generation Workshops



6

IGW's



149

ATTENDEES



35

CONCEPTS

In line with ANZUP's strategic plan to promote and encourage members to bring new concepts forward for idea development, we hold Ideas Generation Workshops.

The workshops are designed to facilitate and support those members who actively contribute in our teleconferences and across our research activities who have an idea they would like to put forward for discussion and, if supported, to further develop into a future grant application.

We also encourage our emerging research, trainee and recent graduate members to attend the workshop(s) as an educational opportunity.



Over the past year, we held six Ideas Generation Workshops, both in person and via Zoom, attracting close to 150 participants and showcased 35 pioneering concepts to our multidisciplinary community.

We look forward to seeing the progression of all the concepts and trials in the coming year.

ANZUP's IGW's 2024/2025

Imaging & Theranostics

Friday 28 June 2024,
ParkRoyal Melbourne
Airport

 **26 attendees**
 **6 concepts**



BUPI

Friday 10 May 2024,
Barangaroo, Sydney

 **19 attendees**
 **7 concepts**



RCC

Friday 17 May 2024,
ParkRoyal Melbourne
Airport

 **20 attendees**
 **5 concepts**

Imaging & Theranostics IGW

Friday 7 March 2025

 **22 attendees**
 **5 concepts**



Germ Cell IGW

Friday 14 March 2025
Peter MacCallum Cancer
Centre, Melbourne

 **25 Attendee**
 **3 concepts**

Prostate IGW

Friday 28 March 2025
Pullman Sydney Airport

 **37 attendees**
 **9 concepts**



CAP MEMBERS AT THE #ANZUP24 ASM

Consumer Advisory Panel Belinda Jago and Ray Allen



CHAIR, BELINDA JAGO



DEPUTY CHAIR, RAY ALLEN

We are the CAP at ANZUP

The Consumer Advisory Panel (CAP) provides ANZUP with invaluable advice on specific studies, general research directions and priorities from a consumer perspective. The CAP also served as a vital communication bridge between ANZUP and the community in order to promote research and engage community support.

Each CAP member brings their own cancer experience, professional expertise, networks, advocacy knowledge and a dedication to the clinical trials research process. Members participate in various ANZUP committees and contribute to many prostate, bladder, kidney, penile and testicular cancer research, advocacy, support and fundraising projects.

Why we are part of the ANZUP CAP

Each member of the CAP has a very personal and life changing experience after being diagnosed with cancer themselves or after a loved one was diagnosed.

We learn a great deal about the “world of cancer”, through tests, treatments or not having access to treatments. While our experiences with the health system can be both positive and negative, we gain significant knowledge from this journey. Our cancer experience gives us a wealth of knowledge, and as I often say, it’s an “unwanted” education. For the CAP, we all want to use our experience to help create a better path for others in the future.

Our Impact: how we make a difference

Each year the CAP participates in a wide range of ANZUP activities that allow us to speak on behalf of the community to provide the patient perspective. We are respected and sought after, and our feedback and opinions matter. The CAP is represented in everything that ANZUP does, which ensures that we are engaged and committed because we feel valued.

Key impact: shaping ANZUP’s Vision - Living life without fear of cancer

During the last 12 months, there has been excellent collaboration with input across all groups associated with ANZUP, including the CAP, to develop the 3-year strategic plan. As part of this, ANZUP wanted to define and articulate its “vision” which had not been done before. The CAP was included in this development and planning. ANZUP had come down to 5 different options for our new vision. The choice was difficult and a decision needed to be made. The CAP was also consulted on the final vision statements, and a beautifully articulated and moving contribution by our member Juliet DeNittis made it clear to all about the choice and the importance of our vision statement. This is only a short part of her response:



“ANZUP has already reduced my fear down to an occasional bit of self-talk while I am living with cancer, so as ANZUP advances

and develops new and/or improved treatments through further research and clinical trials I believe that ANZUP’s vision statement of ‘Living life without fear of cancer.’ is truly inspirational and has my full support.”

If anyone has doubts about the importance of considering a clinical trial as part of your treatment plan, please read Juliet's story. Diagnosed with a rare, aggressive kidney cancer, she found hope through an ANZUP clinical trial. Two years of immunotherapy followed by two treatment-free years have kept her cancer in remission and stable. Now, Juliet leverages her experience with the ANZUP CAP team to advocate for clinical trial access and empower patients in their treatment decisions.

Highlights from the past 12 months

The CAP continues to be actively involved in all of ANZUP's subcommittees, Ideas Generation Workshops, and the Scientific Advisory Committee. This includes reviewing grant applications for the Synchrony Fellowship and Below the Belt Research Fund along with other ad hoc requests to support members with our advice from a community/consumer perspective. There is also an increasing number of the CAP members being part of the grant applications as Chief investigator (CI) or Associate Investigators (AI), and we continue to review Patient Information and Consent forms.

Key events:

#ANZUP24 Annual Scientific Meeting (ASM)

The CAP held its first full day education session at the #ANZUP24 ASM in Gold Coast on Sunday 21st July 2024. With everyone in attendance, this key learning event provided an opportunity to plan for the future, and we benefited from having a full day together.

This Sunday is followed by two days of the ASM, where the CAP is involved in chairing sessions, asking questions of the speakers, and presenting CAP perspectives.

Below the Belt Grant reviews

Ten CAP members took part reviewing 16 Below the Belt research grant applications. Although we review the applications from a consumer perspective, we had excellent alignment with the scientific reviewers once again. The CAP was also instrumental in suggesting and drafting the redesign of the Below the Belt Grant application form. The aim was to give clearer guidance to the applicants about what the lay summary – an easy to understand snapshot of the research project – should include, as the CAP assessment is based on this.

Special mentions:

Consumer's Health Forum (CHF)

CAP members Leonie Young and Melissa Le Mesurier were invited speakers at the recent CHF Webinar – Consumers in Research. They are both excellent expert presenters and ANZUP was featured very well! We cannot thank them enough for what they do and, which highlights the strength of the ANZUP CAP and how involved, valued and respected we are. I did join the webinar and it was a very informative.

International Society for Quality of Life Research (ISOQOL)

Leonie Young was invited to attend the International Society for Quality of Life (ISOQOL) Research meeting held in Germany in October 2024. As Co-Chair of the Patient Engagement Special Interest Group, Leonie reported that she had received good feedback on the work of the ANZUP CAP. ANZUP member A/Prof Sandra Nolte is President-Elect of ISOQOL.

European Society of Clinical Oncology (ESMO) Patient Advocacy Working Group (PAWG)

Greater global collaboration in clinical trials is very important as we aim for better outcomes for patients affected by cancer. But different health systems, drug access, and the legal aspects of clinical trials pose a big barrier. So when an opportunity arose with ESMO offering a couple of new places on the PAWG in the Asia Pacific, we submitted an application for the ANZUP CAP Chair to be considered, and this was approved in January 2025. This is just the beginning. We hope to demonstrate the success of consumer engagement in research at ANZUP and use our model to help increase consumer engagement globally.

A final thank you

The CAP would not exist without the ongoing and wonderful support of the ANZUP Board, Sam Oakes our CEO and the ANZUP team – thank you all.

I personally want to thank the CAP for being the fabulous team that you are. You always answer the call to arms to get our projects done in the best way possible. An extra shout out to Ray, who as deputy always has my back and offers great advice. Each of you brings a unique and valued perspective to the team, and I look forward to collaborating with you all over the coming year.

Publications and Presentations Overview/Highlights

ANZUP has had an outstanding year, marked by significant achievements in both published presentations and publications for its clinical trials.

The organisation has continued to make remarkable strides in advancing cancer research, with numerous groundbreaking studies being showcased at major medical conferences and published in high quality and world renowned journals.

These presentations and publications not only highlight the rigorous work being done within the clinical trial space but also underscore ANZUP's commitment to improving outcomes for people with below the belt cancers.

With each new study and publication, ANZUP reinforces its position as a leader in clinical trial innovation, offering valuable insights that contribute to the global scientific community and, ultimately, to better patient care.

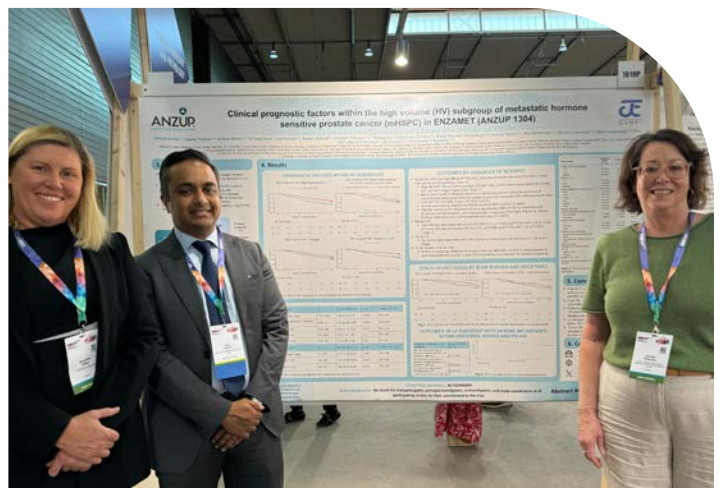
Some of the highlights include:

- Congratulations to our ENZA-p trial team with results featured in The Lancet in April 2024.
- Two posters were presented at ASCO 2024 – TheraP & ENZAMET
- UpFrontPSMA's "remarkable" results were simultaneously published in the leading journal Lancet Oncology and presented at ESMO 2024
- Two posters on ENZAMET were presented
- Interim results from our ENZA-p trial featuring as an oral presentation at ASCO GU 2025
- ANZUP also had 4 posters featured at ASCO GU 2025: P3BEP, WOMBAT, G-DISCO and SUBDUE-3

This year's accomplishments are a testament to the dedication of the ANZUP team and their unwavering focus on advancing cancer treatment through research.



ANZUP AT ASCO GU 2025



DR ANIS HAMID PRESENTED TWO ENZAMET POSTERS AT ESMO 2024.

ANZUP 2024-25

Key Statistics

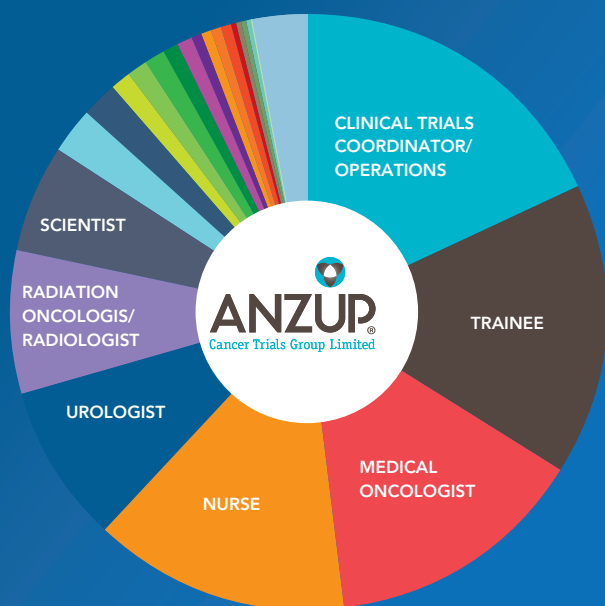
NUMBER OF MEMBERS

AS AT 31 MARCH 2025 ANZUP HAD 2,523 MEMBERS, A 155% INCREASE SINCE 2016.



↑
155%
since 2016

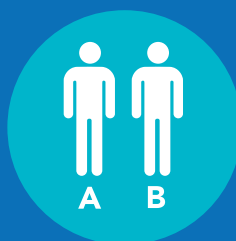
OUR MULTIDISCIPLINARY MEMBERSHIP



CLINICAL TRIALS COORDINATOR/ OPERATIONS	457	FELLOW	21
TRAINEE	405	PATHOLOGIST	20
MEDICAL ONCOLOGIST	356	EXERCISE PHYSIOLOGISTS	16
NURSE	350	PHARMACIST	15
UROLOGIST	219	STATISTICIAN	13
RADIATION ONCOLOGIST /RADIOLOGIST	193	EPIDEMIOLOGIST	12
SCIENTIST	145	ENDOCRINOLOGIST	10
NUCLEAR MED	68	SURGICAL	7
STUDENT	47	DIETICIAN	6
SUPPORTIVE CARE & OTHER	29	HEALTH ECONOMICS	6
RESEARCHER	28	GP	1
PSYCHOLOGIST/ PSYCHIATRIST	24	OTHER	75



35
ANZUP LED & COLLABORATIVE
CLINICAL TRIALS



10,000+
ANZUP TRIAL
PARTICIPANTS



485
2024 ANZUP ASM
DELEGATES

2024 FELLOWSHIPS, SCHOLARSHIPS, AWARDS



INCLUDING BELOW THE BELT RESEARCH FUND, BEST OF THE BEST AWARD, SYNCHRONY FELLOWSHIP, EDUCATION FELLOWSHIP AND STUDY COORDINATOR SCHOLARSHIP.

43

2020

44

2021

36

2022

55

2023

104

2024

ANZUP WEBSITE



171,000

WEB PAGE
VIEWS

3,421

ASM PAGE VIEWS

FROM
1,954
USERS

SOCIAL MEDIA

Nearly
9,000
followers



ACROSS X (TWITTER), BLUESKY, FACEBOOK,
INSTAGRAM, LINKEDIN, AND YOUTUBE –
NEARLY 9,000 FOLLOWERS.

4

2024 BELOW
THE BELT
RESEARCH
FUND GRANTS

Below the Belt

111
YOUR WAY



OVER
\$18,500
RAISED



580
HOURS

OF WORKOUTS,
MEDITATION AND
DANCING WITH KIDS

21,669
KMS



OF WALKING, RIDING
AND RUNNING

1,112
LAPS OF
SWIMMING



Below the Belt MELBOURNE PEDALTHON

146
RIDERS



OVER
\$43,000
RAISED

3,367
LAPS



(10,437.7 KMS)

Membership Educational Events



BEST OF GU ONCOLOGY SYMPOSIUM 2024

ANZUP hosts educational events to nurture the development of its members. These gatherings provide opportunities for professionals to learn, share insights, and stay updated with advancements in research on cancers below the belt.

Best of GU Oncology Evening Symposium

On 20 November 2024, ANZUP hosted its Best of GU Oncology Evening Symposium at Pier One Sydney Harbour, with close to 50 participants. Chaired by Prof Ian Davis and Dr Carole Harris, the event featured speakers including Prof Helen O'Connell (USANZ), Prof Dickon Hayne, Prof Lisa Horvath, Prof Michael Hofman, Prof Manish Patel, and Adj. Prof Samantha Oakes.

BEST OF GU ONCOLOGY SYMPOSIUM 2024



The Symposium covered an array of key topics, from the latest advancements in GU cancers to updates on ANZUP trials and a warm introduction to the forthcoming ANZUP ASM 2025.

The Best of GU Evening Symposium is a collaboration between ANZUP and the Urological Society of Australia and New Zealand (USANZ). The event takes advantage of a smaller meeting, allowing networking in a friendly but focused environment. The program is designed to encourage active audience participation and engagement.



ANZUP thanks our valued supporters of this event:



ANZUP 2024 Bladder and Prostate Masterclass

The ANZUP 2024 Bladder and Prostate Masterclass took place on 28–29 November at the Pullman Sydney Airport. With a focus on the latest trends in prostate and bladder cancer clinical trials research, this event provided a platform to review and discuss datasets from past trials, allowing for a workshop-style session to explore future applications of this valuable data.

Co-convoked by Dr Tahlia Scheinberg and Dr Cam McLaren, the event featured 19 expert speakers and engaged 24 participants. International guests from Malaysia and Germany also joined, reflecting the event's commitment to fostering global collaboration.

This year's Masterclass offered a comprehensive exploration of critical elements in trial design and development. Attendees gained valuable insights into clinical trial grant opportunities, including practical guidance on crafting successful grant submissions.

The program also addressed the intricacies of developing trial protocols, incorporating comprehensive patient-reported outcomes assessments, and integrating health economics analysis to maximize trial impact. Contributions from the ANZUP Consumer Advisory Panel provided essential perspectives on consumer engagement in trial design, further enriching the discussions.



ANZUP thanks our valued supporters of this event:



Fundraising, Partnerships and Engagement

PCFA & ANZUP three-year partnership



Prostate Cancer Foundation of Australia (PCFA) and ANZUP announced a landmark three-year research partnership aimed at accelerating clinical trials and advancements in prostate cancer treatment.

The announcement was made at the Parliamentary Big Aussie Barbie in Canberra on 10 October 2024, with Deputy Prime Minister The Hon. Richard Marles MP, Minister for Health The Hon. Mark Butler MP, Minister for Education The Hon. Jason Clare MP, and Opposition Leader The Hon. Peter Dutton MP among the guests in attendance.

Four-time Logie winner and PCFA Ambassador, Hugh Sheridan, also joined the announcement. Sheridan lost his father Denis to prostate cancer in 2021.

The research collaboration will build on a long-standing relationship between PCFA and ANZUP, who have co-funded clinical trials since 2015. The new partnership underscores PCFA's commitment to innovative research, supported by the PCFA Prostate



Cancer Future Fund, which was established in 2022 to drive national investment in prostate cancer research.

The first tranche of funding under the agreement will involve \$1.2m for clinical trials to try and improve survival outcomes for men with the deadliest forms of prostate cancer.

111 Your Way



ANZUP's personalised and individually run fundraising campaign, Below the Belt 111 Your Way, ran throughout October, empowering participants to raise funds in ways that suited them best.

The campaign aimed to raise awareness and support for the 111 people in Australia and New Zealand diagnosed daily with Below the Belt cancers.

Together, fundraisers achieved incredible milestones, including:

- Over **\$18,500** raised.
- **580 hours** of workouts, meditation and dancing with kids.
- **21,669 kilometres** of walking, riding and running.
- **1,112 laps** of swimming.
- **Creative efforts** such as surfing 111 waves, climbing rocks, capturing wildflower photos, and spreading acts of kindness.

This initiative not only raised vital funds but also generated positive media coverage for ANZUP, reaching nearly half a million people.



Below the Belt Melbourne Pedalthon

The 2024 Below the Belt Melbourne Pedalthon took place on 21 April 2024 at Sandown Racecourse and was a tremendous success. A total of 146 riders completed an incredible 3,367 laps, covering a staggering 10,437.7 km. We're thrilled to announce that we've surpassed \$43,000 in funds raised – an amazing achievement!

The Results

- Highest Fundraiser – Individual: Darren Smith with \$2,868 raised
- Highest Fundraiser – Team: Shaw Contract/Hot Black with over \$4,596.64 raised
- Most Number of Laps – Individual: David Pook with 37 laps in 3 hours and 4 minutes.
- Most Number of Laps – Team: GOG – Having a Ball, as a team of 4 with 147 laps.
- Fastest Lap by Individual – Male: Josh Hardy-Brown with 4 minutes and 9 seconds
- Fastest Lap by Individual – Female: Melissa McKenzie with 4 minutes and 41 seconds
- Sprint Challenge Champion: David Bunning
- Fundraising Competition Winner: Andrew Batch (the top fundraiser from April 3rd to 15th)

Acknowledgement

Special thanks to our members David Pook, Andrew Weickhardt and Jeremy Shapiro who proved their dedication to ANZUP by getting some teams together and partaking in the ride.

Thank you to James Buteau, David Homewood, Shomik Sengupta, Labor MP Eden Foster, and Deputy Mayor Cr Ricard Lim for their inspiring speeches and warm welcomes during the awards ceremony.

Gratitude to Mobile Healing Hands for easing sore muscles, The Flying Bike mechanic for keeping bikes in top shape, and DJ Beth Grace for keeping the energy high.

A heartfelt thanks to our incredible staff, volunteers, and MRC venue supporters for making this event a resounding success – we couldn't have done it without you.

Venue Supporter:



2024 Supporters:



Community Fundraising

Andrew Batch proved his dedication to supporting ANZUP by enthusiastically participating in our Below the Belt Melbourne Pedalthon 2024.

Andrew is a dual cancer survivor having been diagnosed with kidney cancer in October 2022 resulting in his right kidney being removed with a 1kg tumour in it. Just one month later, Andrew was diagnosed with an aggressive form of prostate cancer which metastasised in his bones. A combination of chemotherapy and hormone therapy has helped greatly.

"I am now an advocate for telling people I meet to get regular testing and not ignore any health issues. I don't want them to end up learning the mistakes I made. I feel if us guys can start talking more freely about such issues, it can only lead to better outcomes"
– Andrew Batch

Grants and Awards 2024 - 2025

Infrastructure Grants

Funds provided by Cancer Australia to support ANZUP's infrastructure up until December 2021 were managed by the University of Sydney and not reported in the financial accounts of ANZUP unless transferred in support of specific expenses incurred by ANZUP.

In July 2024 ANZUP was successful in our 2024-2027 Support for Cancer Clinical Trials grant application and ANZUP will administer this grant.

Other Grants/ Funding during the 2024-25 period are outlined below.

Infrastructure Funding

Cancer Australia Infrastructure Grant: 1 July 2024 to 30 June 2027, AUD\$1,585,145 awarded to ANZUP. During this reporting period ANZUP received AUD\$516,250 and is reported in the Annual Accounts.

There is another AUD\$100,000 received this period, which belongs to the previous contract (for the 1 January 2022 to 30 June 2024 period)

Research Grants

Funds provided by Cancer Australia, the National Health and Medical Research Council, philanthropic funding bodies and pharmaceutical companies in support of ANZUP trials managed by the University of Sydney, are not reported in ANZUP's financial accounts. Funds to support ANZUP sponsored trials and site payments, insurance and other trial related costs are transferred to ANZUP and are reflected in these accounts.

ANZUP grant income and expenditure during this reporting period are included in the 2024/2025 financial accounts. Grants awarded to ANZUP Cancer Trials Group during this reporting period are listed below:

ANZadapt: Phase II randomised controlled trial of patient-specific adaptive versus continuous Abiraterone or enzalutamide in metastatic castration-resistant prostate cancer.

Funding by ACF (Anti Cancer Foundation) EUR\$ 647,498. During this reporting period AUD\$220,000 was transferred to ANZUP and reported in the annual accounts.

BCG+MM: Adding mitomycin to BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer: a 2-stage, randomised phase 3 trial. Funding by NHMRC AUD\$1,587,163.80. (2019 – 2023). During this reporting period AUD\$170,947 was transferred to ANZUP and reported in the annual accounts.

CLIMATE: Assessing the Clinical utility of miR-371a-3p as a marker of residual disease in Clinical Stage 1 Testicular Germ Cell Tumour, following orchidectomy. Funding by Ben Tran AUD\$150,000, ANZUP Below the Belt 2019 AUD\$50,000 and ANZUP Discretionary Funding AUD\$250,000.

During this reporting period AUD\$62,000 was transferred to ANZUP and reported in the annual accounts.

DARO-lipid: During this reporting period AUD\$90,000 and USD\$132,456 was transferred to ANZUP and reported in the annual accounts.

DASL-HiCaP: A randomised phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer. Funding by Bayer USD\$53,173,088. During this period USD\$140,000 and AUD\$2,850 was transferred to ANZUP and reported in the annual accounts.

ENZAMET: A randomised phase III trial of Enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer. Funding by Astellas AUD\$19,962,490 (2014-2022). During this reporting period USD\$89,868 was transferred to ANZUP and was reported in the annual accounts.

ENZAMET Translational Research Program: During this reporting period AUD\$366,110 and USD\$1,152,512 was transferred to ANZUP for TR Execution Milestone Direct Costs and was reported in the annual accounts.

ENZA-p: A randomised phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castration resistant prostate cancer treated with enzalutamide. Funding by

Prostate Cancer Research Alliance: The Australian Government and Movember Foundation Collaboration AUD\$4,000,000; Endocyte USD\$320,000; St Vincent's Clinic Foundation AUD\$400,000; GenesisCare AUD\$300,000; and Roy Morgan Research Ltd AUD\$300,000; (2020-2024). During this period USD\$156,263 was transferred to ANZUP and reported in the annual accounts.

ENZARAD: A randomised phase III trial of Enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised prostate cancer. Funding by Astellas AUD\$13,184,412(2014-2022). During this period USD\$17,000 was transferred to ANZUP and reported in the annual accounts.

EVOLUTION: A randomised phase II trial of Radionuclide ¹⁷⁷Lu-PSMA Therapy versus ¹⁷⁷Lu-PSMA in Combination with Ipilimumab and Nivolumab for Men with Metastatic Castration Resistant Prostate Cancer (mCRPC). Funding by Prostate Cancer Foundation of Australia AUD\$1,500,000; Bristol Myers Squibb USD\$1,296,698, Novartis USD\$320,000, (2021-2024). During this reporting period ANZUP received AUD\$100,000 and is reported in the annual accounts.

Geni-AIRSPACE: A three-part, sequential, multi-centre, open label randomised controlled trial (1:1) of risk stratification by three molecular tests to inform decision-making in people with clinically localised FIR CaP. During this reporting period no funds were transferred to ANZUP.

GUIDE: A randomised non-comparative phase II trial of biomarker-driven intermittent docetaxel versus standard-of-care (SOC) docetaxel in metastatic castration-resistant prostate cancer (mCRPC) Funding by Chris O'Brien Lifehouse Philanthropic \$AUD450,000, ANZUP Belt the Belt Research Fund AUD\$50,000 and ANZUP discretionary funding AUD\$350,000. During this reporting period no funds were transferred to ANZUP.

KEYPAD: A phase II trial using denosumab and pembrolizumab in clear cell renal carcinoma. Funding by Merck Sharpe Dohme and Amgen AUD\$2,454,925. During this reporting period no funds were transferred to ANZUP.

PCR-MIB (& PCR-MIB TR): Pembrolizumab With Chemoradiotherapy as Treatment for Muscle Invasive Bladder Cancer. During this reporting period AUD\$57,762 was transferred to ANZUP and was reported in the annual accounts. Also during this reporting period AUD\$325,340 for Translational Research was transferred to ANZUP and was reported in the annual accounts.

PET-MET: Retrospective analysis of the ENZAMET cohort - Utility of PSMA PET scan quantitation and CT radiomics as prognostic and predictive biomarkers. Funding by Astellas AUD\$550,000. During this reporting period ANZUP received AUD\$40,000 and is reported in the annual accounts.

RAMPART: Renal Adjuvant MultiPle Arm Randomised Trial (RAMPART) An international investigator-led phase III multi-arm multi-stage multi-centre randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse. Funding by UCL AUD\$2,080,000. During this reporting period ANZUP received USD\$87,200 and is reported in the annual accounts.

RetroPSMA: During this reporting period ANZUP received AUD\$270,000 and is reported in the annual accounts.

TIGER: A Randomised Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilising Paclitaxel plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumours (ANZUP 1604). Funding received from the Movember Foundation \$454,803.74. During this reporting period ANZUP received AUD \$33,995 and is reported in the annual accounts.

UNISoN: Phase II sequential cohort trial of Single Agent Nivolumab, then Combination Ipilimumab + Nivolumab in metastatic or unresectable non-clear cell renal cell carcinoma (ANZUP 1602). Bristol Myers Squibb (BMS) provided funding USD\$1,681,822 and product to support the UNISoN trial. During this reporting period ANZUP received no funds reported in the annual accounts.

UNICAB: A phase II trial of single agent cabozantinib in patients with locally advanced or metastatic non-clear cell renal cell carcinoma post immunotherapy or who are unsuitable for immunotherapy (ANZUP 1801). AUD\$30,000 was received in this reporting period.

WOMBAT: During this reporting period ANZUP received AUD\$586,519 and is reported in the annual accounts.



Below the Belt Research Fund 2024

The Below the Belt Research Fund provides much needed seed funding to support ANZUP members to progress new trial ideas to the point of becoming full scale studies. It has supported many members in the development of investigator-initiated studies. Below are the 2024 recipients of the Below the Belt Research Grants.

Below the Belt
Research
Fund

Arti Raghobar

Defining the kidney cancer microenvironment

Kidney cancer affects many Australian adults, yet consistent and effective treatments remain elusive. Unlike other cancers that respond well to targeted therapies, kidney cancer lacks such options. To bridge this gap, we must explore the cancer cells and the surrounding non-cancer cells within the tumour microenvironment. Since cancer cells do not act in isolation, they interact with neighbouring immune cells, blood vessels and normal kidney cells. We hypothesise that different cell types, their position and interactions within the kidney tumour microenvironment directly impact treatment response. This research will focus on uncovering the gene (or the active regions of our DNA) and protein (or the final gene products) in individual cells located within the kidney tumour microenvironment using 10x Genomics Xenium technology. In brief, Xenium captures specific genes, proteins and their position within thin slices of kidney tumour tissue. This captured gene, protein and cell position information is used to explore the cell-to-cell interactions within the kidney tumour microenvironment. In this manner, we will investigate the complex interactions between the different cell types and their specific positions within the tumour to understand



the treatment responses of participants from the UNISON and KEYPAD clinical trials. Our short-term research goal is to identify gene and protein expression, cell location and interactions within the kidney tumour microenvironment. This information will help us understand the biological effects of the offered treatment in the UNISON and KEYPAD clinical trials. In the long term, this gene and protein expression data will be utilised to predict drug response before kidney cancer clinical trials begin.

Cynthia Hawks

Gemcitabine-Docetaxel Intravesical Instillation SynChronously – a Phase I study (G-DISCO)

This project is a Phase 1 investigator led project. Phase 1 studies are small studies that help determine if a new treatment is safe. This project is investigating a new method of giving combination intravesical chemotherapy (putting, or instilling, the drugs directly into the bladder via a catheter) to patients with high risk non-muscle invasive bladder cancer (HRNMIBC). The treatment will be in patients where the cancer returned despite the usual first line therapy into the bladder with Bacille Calmette Guérin (BCG) (the current first line “gold standard” treatment) or in those who can’t have BCG. Current usual practice is to give two chemotherapies, gemcitabine and then docetaxel, one after the other. Gemcitabine is put in first then left in for two hours. It is then drained out and docetaxel put in and left for a further two hours, the whole process taking near to 5 hours. This project will assess the safety, tolerability and feasibility of synchronous administration of intravesical gemcitabine and docetaxel. Both agents will be instilled into the bladder together and will then remain together in the bladder for



the recommended dwell time of two hours. This project will record Patient Reported Outcomes (PRO's), side effects, the rate of completing 6 treatments given weekly, and cancer recurrence rates. At the completion of this 6-week induction regime patients will undergo a cystoscopy (camera into the bladder) under general anaesthetic and bladder biopsies will be taken which is the standard practice after intra-vesical chemotherapy.

Vinod Subhash

Extracellular vesicle Informed Therapeutics in Prostate Cancer

Prostate cancer is one of the most common cancers worldwide, significantly impacting both quality of life and mortality. Traditional treatments, including surgery, radiation, and chemotherapy, often come with severe side effects and varying effectiveness. The EXIT PC project aims to improve treatment outcomes and survival in prostate cancer by leveraging extracellular vesicles to develop informed and personalized therapeutic strategies. Extracellular vesicles (EVs) are tiny, naturally occurring vesicles secreted by cells that play a crucial role in cell-to-cell communication. They contain a wealth of information, including proteins, lipids, and genetic material (DNA, RNA), which reflect the condition of their cells of origin. In the context of cancer, EVs released by tumour cells can provide critical insights into the tumor's behaviour, progression, and response to treatments. By analysing the EVs present in the blood of ENZAMET (ANZUP 1304) patients, this study aims to obtain a non-invasive “snapshot” of the tumor's molecular landscape. This approach



could help identify novel biomarkers associated with prostate cancer, aiding in early diagnosis, and monitoring treatment resistance and disease progression. EXIT PC would broaden ANZUP's capacity to analyze circulating biomarkers in blood. By decoding the molecular messages carried by EVs, this precision medicine approach has the potential to improve the efficacy of treatments and enhance the overall quality of life for people diagnosed with prostate cancer.

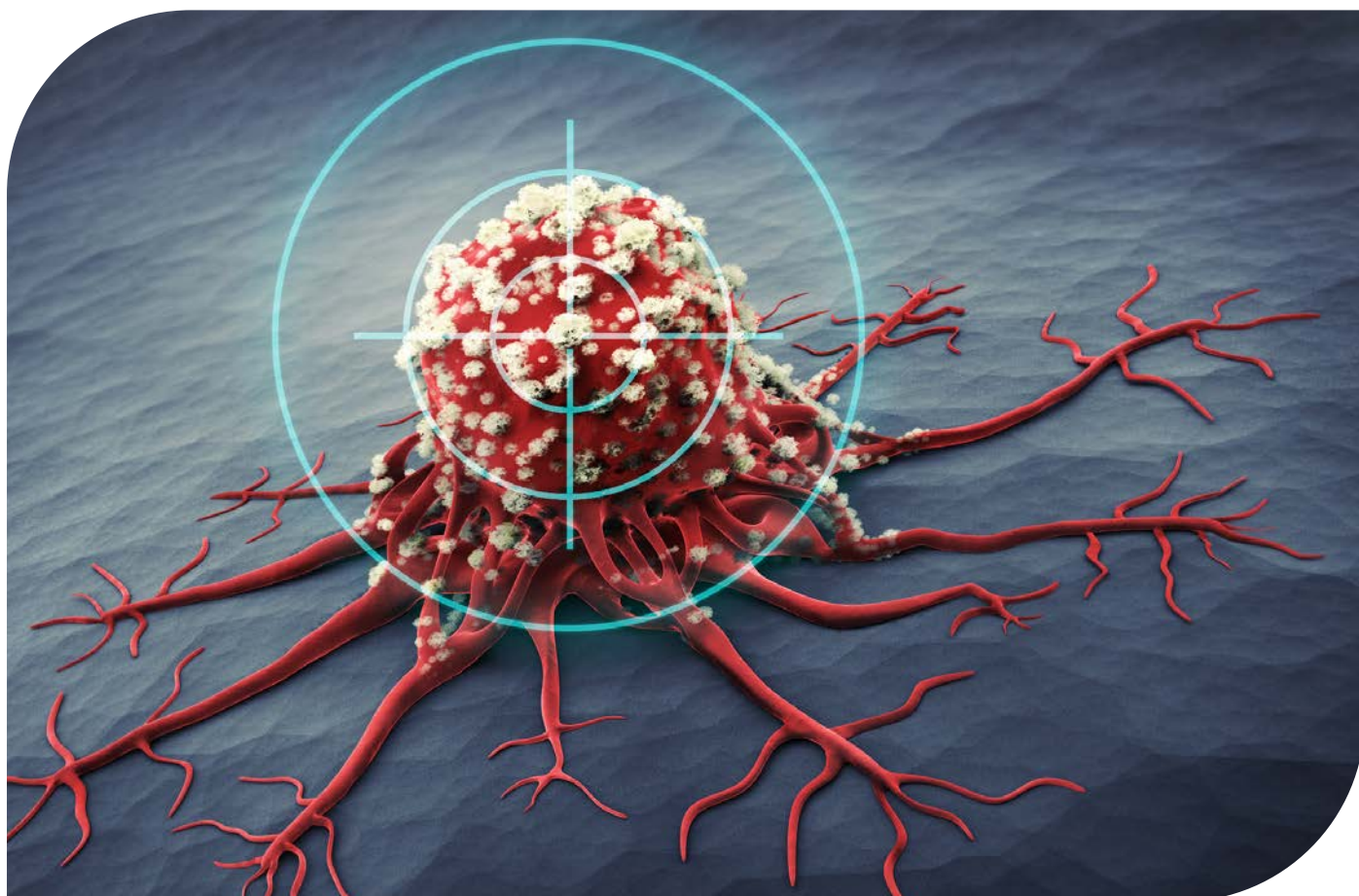
Weranja Ranasinghe

Evaluating the BCG-R5 immune marker to define BCG response in high-risk non-muscle invasive bladder cancer and personalise intravesical therapy

The majority (80%) of newly diagnosed bladder cancers are limited to superficial layers of the bladder. Patients with these aggressive superficial bladder cancers are commonly treated with an immunotherapy medication called BCG, which is put into the bladder. BCG is the inactivated tuberculosis bacterium (BCG) that stimulates the body's immune cells to attack the tumour cells and has been used effectively for decades. However, in 30-45% of patients, this BCG treatment will fail, with the cancer progressing into deeper layers or spreading outside the bladder despite treatment. If the cancer progresses to the bladder muscle despite BCG, even curative treatments such as removal of the bladder result in poor outcomes. Yet, currently, there are no biomarkers to identify which patients will not respond to BCG treatment. The funding from the Below the Belt Award in 2022 allowed Dr Ranasinghe and colleagues to identify that BCG was ineffective in activating immune cells in BCG-unresponsive tumours because these tumours have low levels of inflammatory immune cells, which are exhausted



(accepted for ANZUP 2024). Therefore, by staining five immune cell types, a biomarker was developed, BCG-R5, which could predict response to BCG therapy in patients with aggressive superficial bladder cancer. The proposed study aims to validate the BCG-R5 biomarker combination. Recent studies also suggest that the chemotherapy combination of Gemcitabine-Docetaxel (Gem-Doce) is an alternative to BCG, so the investigators aim to evaluate the utility of the BCG-R5 immune marker in patients undergoing Gem-Doce.



Synchrony Fellowship Award

Thanks to the generous ongoing support of the Synchrony Foundation, we established the Synchrony Fellowship Award.

The Synchrony Fellowship Award provides support for prostate and urogenital cancer research support driven by a defined clinical question.

The Award is up to \$500K over two years (supporting two projects) and provides salary support for the researchers as well as some direct research costs towards the projects.

We are delighted to announce that Dr Wee-Kheng Soo is the recipient of the 2024 Synchrony Fellowship Award.

Dr Wee-Kheng Soo (2024 Recipient)



DR WEE-KHENG SOO

Dr Wee-Kheng Soo's research is focused on improving health outcomes for older people with cancer in healthcare systems within Australia and on a global scale. During his PhD, he made substantial contributions to geriatric oncology by leading the INTEGERATE Study – a landmark randomised controlled trial that showed the effectiveness of geriatric assessment and oncogeriatric management for

older patients receiving anticancer treatment – and through developing and validating the Elderly Functional Index. His research work (24 publications) has been translated into clinical resources and used to inform health service design to improve the quality of care for older people with cancer. Currently, he leads the Ageing Resiliency in Cancer clinics as a medical oncologist and geriatrician.

Project Title:

Developing a Quality of Life-derived Frailty Index and assessing the effects of Enzalutamide and Comprehensive Geriatric Assessment on Frailty and Resilience in Prostate Cancer and Older Cancer Patients: insights from the ENZAMET and INTEGERATE randomised controlled trials



Project Overview:

Cancer treatment can be challenging, and some people do not complete treatment or have poor quality of life as a result. This project introduces an innovative approach to measuring a patient's frailty—their health vulnerability to treatment—by focusing on their quality of life. Traditional assessments based on medical tests and physical checks often overlook how patients feel about their health and quality of life. This initiative seeks to develop a "Quality of Life-derived Frailty Index" by analysing responses from quality of life questionnaires to integrate the patient's insights on their well-being and ability to manage daily challenges into a measurable frailty metric.

The concept will be tested with existing data from two pivotal clinical trials, ENZAMET and INTEGERATE. ENZAMET trial data will be used to look at how a common prostate cancer treatment called enzalutamide affects prostate cancer patients' frailty levels and assess its suitability for patients with varying degrees of frailty. INTEGERATE trial data will be used to look at the role of comprehensive geriatric assessments in helping older people with cancer feel less frail. Together, the idea is to find out if understanding more about a patient's quality of life and frailty can guide personalised care plans, supporting patients in managing their treatment and maintaining well-being afterwards.

By emphasising a more person-centred approach in cancer care, this project aims to improve health outcomes for vulnerable patients and align with a compassionate care model that prioritises what patients consider most important, striking a balance between life extension and quality of life. This approach has the potential to change how clinicians assess frailty and plan cancer treatment, making a meaningful difference in the lives of many.

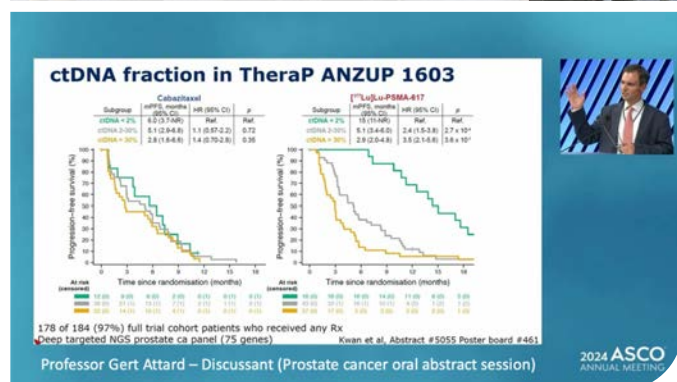
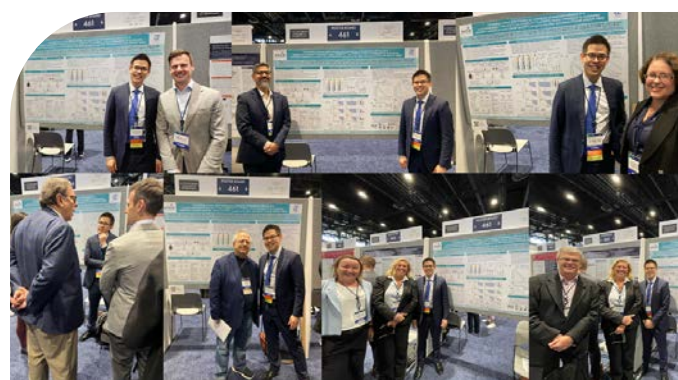
Dr Edmond Kwan (2023 Recipient)



DR EDMOND KWAN

Dr Edmond Kwan is a clinician-scientist and consultant medical oncologist at Eastern Health in Melbourne. He is currently serving as Laboratory Head and Senior Research Fellow at the Eastern Health Clinical School, with a cross-appointment at the Monash Biomedicine Discovery Institute. Dr Kwan has maintained strong links to patient care, serving as a Principal Investigator on early and late-phase clinical

trials in prostate, bladder, and kidney cancer. He is also on the translational research subcommittee of several ANZUP-led trials, including TheraP, ENZARAD and DASL-HiCaP.



Project title:

Multimodal ctDNA analysis and novel imaging to inform precision use of PSMA radioligand therapy: an integrative biomarker analysis of the phase 2 TheraP trial

Project Update:

Lutetium-177 PSMA (LuPSMA) is a new innovative intravenous therapy that delivers targeted radiation to advanced prostate cancer cells, offering hope where traditional treatments fail. Unfortunately, not all patients benefit, and access to this life-prolonging therapy is limited. Better ways to identify which patients will respond to LuPSMA treatment are urgently needed. A simple blood test may hold the answer. Cancer cells shed fragments of tumour DNA into the bloodstream, known as circulating tumour DNA (ctDNA). In some cancers, it is now possible to use ctDNA 'liquid biopsy' to help predict which patients are most likely to benefit from treatment.

With support from the Synchrony Fellowship, I collaborated with a team of genomic scientists from the Vancouver Prostate Centre (led by A/Prof Alex Wyatt) in a world-first study analysing nearly 300 blood samples from participants in the Australian TheraP clinical trial. We aimed to determine whether ctDNA could identify patients most likely to benefit from LuPSMA. We discovered that patients with low ctDNA levels had far better outcomes with LuPSMA than traditional chemotherapy, making this the first blood-based marker to guide treatment decisions between two effective prostate cancer therapies. We also identified genetic markers linked to LuPSMA success or failure, and uncovered how resistance develops over time. These findings have the potential to improve clinical care, as ctDNA technologies are increasingly available to doctors in the clinic. Integrating ctDNA testing into routine practice could help doctors personalise prostate cancer treatment, reduce unnecessary side effects by stopping futile treatments sooner, and optimise the use of healthcare resources – ensuring LuPSMA reaches those most likely to benefit.

Pleasingly, our research has gained international recognition, being presented at the 2024 American Society of Clinical Oncology Annual Scientific Meeting and highlighted on both the UroToday platform and Uromigos podcast. Furthermore, the TheraP ctDNA work has been accepted for publication in Nature Medicine. I am profoundly grateful for the support of the Synchrony Fellowship, which made this collaboration with world-leading scientists possible. The blood samples donated by TheraP trial participants represent one of the most unique datasets worldwide – a precious gift that has enabled discoveries with far-reaching implications. This work has not only advanced precision medicine for prostate cancer but has provided me with protected research time to establish my own group in Australia, where I now focus on translating these findings to improve care for patients with advanced prostate and bladder cancers.

ANZUP / PCFA Partnership Grant

Building on the landmark three-year partnership between the Prostate Cancer Foundation of Australia (PCFA) and ANZUP, we launched a dedicated grant program. This initiative fosters the development of ANZUP sponsored protocols by providing researchers with multidisciplinary feedback from senior investigators, statisticians, consumers, and trainees.

The inaugural grant was awarded to Professor Shahneen Sandhu for the study EVOLUTION.

Shahneen Sandhu (2024 Recipient)



PROF SHAHNEEN
SANDHU

Professor Shahneen Sandhu is a Consultant Medical Oncologist and researcher in the Melanoma and Uro-oncology units at the Peter MacCallum Cancer Centre. She is the Research Lead for the Melanoma Medical Oncology Service.

Professor Sandhu sits on multiple international advisory panels and has been principal investigator on multiple investigator-initiated and practice changing

registration studies in melanoma and prostate cancer. She leads clinical, translational and laboratory research in skin cancers and prostate cancer with a major focus on designing and conducting biologically driven clinical trials to translate laboratory findings into new clinical treatments and studying biomarkers of response and resistance to treatment.

Project Title:

EVOLUTION: A randomised phase II trial of Radionuclide ¹⁷⁷Lu-PSMA Therapy versus ¹⁷⁷Lu-PSMA in Combination with Ipilimumab and Nivolumab for Men with Metastatic Castration Resistant Prostate Cancer (mCRPC). (ANZUP 2001)

Project Overview:

The aim of this study is to see if combining ipilimumab and nivolumab (drugs that activate the body's own immune response to kill cancer cells), with Lu-PSMA (a type of treatment called radionuclide therapy that can be used to treat prostate cancer by bringing radioactive atoms into the cancer cells), can further improve the anti-cancer effects of Lu-PSMA. It is thought that ipilimumab and nivolumab and Lu-PSMA may work together to treat prostate cancer. Lu-PSMA can potentially kill cancer cells and break up the tumour into small pieces that may be recognised by your immune system while ipilimumab and nivolumab help activate the immune system to find and attack the cancer. This new treatment combination may lead to shrinkage or stabilisation of previously progressing tumours and therefore hopefully stop or reverse the growth of the cancer.

The EVOLUTION trial is now closed to recruitment and enrolled 93 people from across Australia.

Noel Castan Fellowship



The Noel Castan Fellowship, established by Anita Castan in memoriam of her husband who passed away from cancer, serves to bolster ANZUP's research capabilities. This initiative aims to enhance the translation of trial data into actionable insights, ultimately contributing to the advancement of optimal patient care.

Hui-Ming Lin (2020 Recipient)



HUI-MING LIN

Hui-Ming is originally from Malaysia and obtained a PhD in Molecular Medicine from the University of Auckland in 2010. She did her postdoctoral research with Prof Lisa Horvath's Advanced Prostate Cancer research group at the Garvan Institute of Medical Research. In 2024 she obtained a Graduate Diploma in biostatistics from the University of Sydney through part-time study. She continues working for Prof

Horvath, analysing molecular and clinical data for biomarkers in prostate cancer.

Project Title:

'Bioinformatics' project is an analysis of the lipidomic and cytokine profiles from ANZUP's ENZAMET study, which may identify novel biomarkers from the enzalutamide response, and provide new therapeutic targets to overcome enzalutamide resistance to improve the outcome of prostate cancer patients.

Outcomes from the Noel Castan Fellowship:

The Noel Castan Fellowship has enabled me to perform research on biological markers in blood specimens from the ENZAMET trial. The ENZAMET trial, which was led by ANZUP, is an international Phase 3 trial on 1125 men with metastatic hormone-sensitive prostate cancer (mHSPC). The trial showed that addition of enzalutamide to standard testosterone suppression improved survival and delayed clinical progression. However, not all men responded to enzalutamide, and responders eventually stop responding.

The aim of my project under the Noel Castan Fellowship was to look for biological markers in blood that can predict who will respond to enzalutamide, as this may help decide the best course of treatment and lead to new treatments for improving response. The biological markers I studied were lipids (fat molecules) and cytokines (chemical messengers for immune cells).

When I started the project, the retrieval of ENZAMET blood samples from multiple international trial sites was delayed by the COVID pandemic. Thus in the meantime, I prepared the analytical pipeline and statistical algorithms for the project by performing a similar study on a smaller cohort of Australian men with castration-resistant prostate cancer (CRPC). The results were published in "Lin et al (2021) Cancers (Basel) 13:4964. Relationship between circulating lipids and cytokines in metastatic castration-resistant prostate cancer".

Finally in mid 2023, we started processing the ENZAMET blood samples for my project. By January 2024, the profiling of 823 lipids and 15 cytokines were completed. With the lipid data, I showed that a lipid biomarker (PCPro) which we had previously developed for metastatic castration-resistant prostate cancer (mCRPC), was also prognostic in mHSPC. These findings are extremely exciting because we are also investigating if PCPro can be used as an indicator for personalised metabolic therapy in metastatic prostate cancer. The findings were presented as a poster at the European Society for Medical Oncology in 2024 – "Horvath et al, Association of the lipid biomarker, PCPro, and clinical outcomes in the ENZAMET trial (ANZUP 1304)". A manuscript is currently under review by a journal with myself as the first author. I have also derived new prognostic lipid signatures for mHSPC (unpublished yet). Analysis of the cytokine data is still ongoing, and the results are looking interesting.

The fellowship ended in June 2024 which, later than originally planned due to COVID delays. Nevertheless, the project is still ongoing through other fundings as the data analysis is not completed. I am extremely grateful for the fellowship as it enabled me to work on this exciting research project with results which may improve clinical outcomes in metastatic prostate cancer.

Hui-Ming Lin



Kath Schubach (2022 Recipient)



KATH SCHUBACH

Kath Schubach is a GU clinical nurse practitioner practising in private practice in metropolitan Melbourne and regional Victoria. Her clinical work involves assessing and supporting patients with newly diagnosed cancer. She has 25 years of experience and qualifications working across two core disciplines: cancer and urology. Kath Schubach has a master's in Nursing Science and postgraduate qualifications in

oncology, urology, continence nursing. She is in the third year of her PhD at Flinders University. Her thesis is titled, The Supportive Care Needs of People Diagnosed and Living with Non-muscle Invasive Bladder Cancer and the Perceived Impact on Their Health-related Quality of Life – a multi-method study.

Project Title:

The supportive care needs of patients diagnosed and living with non-muscle invasive bladder cancer and the perceived impact on their health-related Quality of life: A Multi-method study.

Project Update:

This progress report outlines activities from April 2024 to the present.

I am in my third year of my doctorate studies and have moved to Flinders University. I now have two publications accepted into Q1 Journals. I have ethics approval to commence work on the baseline Health-related Quality of life data from the ANZUP BCG/MM clinical trial.

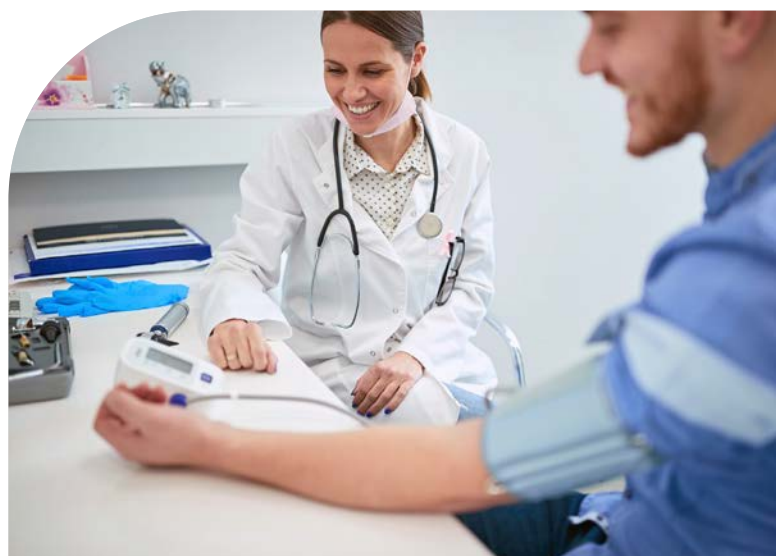
I continue to work as a Urology Nurse Practitioner, providing clinical support to men and women with urological issues. The generosity of the Noel Castan Fellowship enables me to get financial support to provide time off in my clinical role to fully commit to my studies. It also gives me the financial resources to attend classes/courses that will assist with my thesis completion.

Milestones Achieved in 2024:

- Manuscript 2 accepted for publication in the Journal of Cancer Survivorship
- Poster Presentation at the European Association of Urology Nurses Conference, Paris 2024 – Awarded Best Scientific Poster
- PhD update at ANZUP ASM 2024 Nurses Education Day
- Invited speaker for the New Zealand Urology Nurses Webinar in June 2024 – Presented my systematic review on the supportive care needs of the NMIBC population
- Currently working on my third publication, investigating the QoL of NMIBC participants using baseline data from the ANZUP/NHMRC BCG/MM clinical trial
- Preparing to submit this article for publication in July 2025
- Commencing the ethics application for a qualitative paper

I anticipate concluding my project in 2026 or early 2027. I will continue to submit abstracts to relevant conferences, both locally and internationally, throughout my candidature.

Kath Schubach, PhD Candidate



2024 ANZUP ASM



Message from #ANZUP24 Co-Convenors

On behalf of the organising committee, we are delighted to share the highlights of the #ANZUP24 ASM, held from 21-23 July 2024 in Gold Coast, themed 'Making Waves'. ANZUP has continued to make waves in the genitourinary (GU) cancer community. We recognise the ups and downs experienced by our patients, their families and our research community. We also believe riding the waves of innovation is far more rewarding than staying stagnant.

This dynamic event provided a platform for discussing and presenting the latest advancements in GU cancer treatment, research, and supportive care.

We were honoured to host 96 national speakers who contributed to a variety of sessions, reflecting the diversity of ANZUP's membership, which now exceeds 2,400 members.

Our international faculty played a crucial role in providing a global perspective on the challenges faced by GU cancer experts. We extend our gratitude to Dr Cristiane Bergerot, Dr Elena Castro, Prof Paul Nguyen, Prof Ravindran Kanesvaran, Dr Rob Hamilton, and Prof Bertrand Tombal for their invaluable contributions.

The diverse sessions included:

- The Perfect Pitch
- Nurses & Allied Health Symposium
- Translational Highlights Session
- ANZUP MDT Masterclass
- Translational Science and Supportive Care Breakfast Sessions
- Best of the Best Oral Abstracts Session
- ANZUP Trials in Action Session

These sessions were both informative and thought-provoking, catering to a wide range of interests and expertise. Over three days, delegates had the chance to learn from and interact with experts and leaders in GU cancer research, diagnosis, treatment, and management. Attendees also gained insights into ongoing and upcoming ANZUP trials.

We are proud to report that the #ANZUP24 ASM set a new record with an attendance of 485 delegates and received 84 abstract submissions. This impressive turnout highlights ANZUP's reputation for delivering high-quality, academically rigorous, and entertaining ASMs.

In addition, this year's ASM saw remarkable engagement on X (Twitter), with close to 2 million #ANZUP24 impressions and over 500 posts. The high level of interaction on social media was a testament to the event's impact and reach.

Thank you to every speaker, sponsor, chair, delegate, participant, committee member and organiser for your valuable contributions to the success of the #ANZUP24 ASM. We hope you enjoyed the event in the city of surfing, waves and sunshine (even in winter), and we look forward to seeing you in Sydney for the #ANZUP25 ASM.

Warm regards,
Matt Roberts & Aaron Hansen
#ANZUP24 ASM Co-Convenors





Sponsor Acknowledgements

ANZUP gratefully acknowledges the generous support of our 2024 ASM sponsors.

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EXHIBITION TRADE TABLES



Appendix – Publications and Presentations

Publications

Overall survival and quality of life with [¹⁷⁷Lu]Lu-PSMA-617 plus enzalutamide versus enzalutamide alone in metastatic castration-resistant prostate cancer (ENZA-p): secondary outcomes from a multicentre, open-label, randomised, phase 2 trial

ENZA-p
The Lancet
14 FEB 2025

Overall survival and quality of life with [¹⁷⁷Lu]Lu-PSMA-617 plus enzalutamide versus enzalutamide alone in metastatic castration-resistant prostate cancer (ENZA-p): secondary outcomes from a multicentre, open-label, randomised, phase 2 trial

ENZA-p
The Lancet
13 FEB 2025

Enzalutamide with standard first-line therapy for metastatic hormone-sensitive prostate cancer: a plain language summary of the ENZAMET trial (ANZUP 1304)

ENZA-p
Future Oncology
23 JAN 2025

Enzalutamide in metastatic hormone-sensitive prostate cancer: A plain language summary of the ARCHES and ENZAMET follow-up studies

ENZAMET
Future Oncology
23 JAN 2025

Adapting the design of the ongoing RAMPART trial in response to external evidence: An example for trials which take many years to run and report

RAMPART
Elsevier
18 OCT 2024

Survival of men with metastatic hormone-sensitive prostate cancer and adrenal-permissive HSD3B1 inheritance

The Journal of Clinical Investigation
18 SEP 2024

Sequential [¹⁷⁷Lu]Lu-PSMA-617 and docetaxel versus docetaxel in patients with metastatic hormone-sensitive prostate cancer (UpFrontPSMA): a multicentre, open-label, randomised, phase 2 study

UpFrontPSMA
The Lancet
16 SEP 2024

Pembrolizumab with Chemoradiation as Treatment for Muscle-invasive Bladder Cancer: Analysis of Safety and Efficacy of the PCR-MIB Phase 2 Clinical Trial (ANZUP 1502)

PCR MIB
European Association of Urology
21 JUN 2024

Management of advanced prostate cancer in the Asia-Pacific region: Summary of the Asia-Pacific Advanced Prostate Cancer Consensus Conference 2023

Other
Wiley
18 APR 2024

[¹⁷⁷Lu]Lu-PSMA-617 plus enzalutamide in patients with metastatic castration-resistant prostate cancer (ENZA-p): an open-label, multicentre, randomised, phase 2 trial

ENZA-p
The Lancet
12 APR 2024





Presentations

Bipolar androgen therapy (BAT) for nonmetastatic castration-resistant (M0 CRPC) prostate cancer progressing on darolutamide: Working Out M0 BAT (WOMBAT; ANZUP 2201)

ASCO GU 2025
14 FEB 2025

Trials in Progress

P3BEP (ANZUP 1302): An international randomized phase 3 trial of accelerated versus standard BEP chemotherapy for individuals aged 11-50 years with intermediate and poor-risk metastatic germ cell tumours

P3BEP
ASCO GU 2025
14 FEB 2025

Gemcitabine-Docetaxel Intravesical instillation Synchronous CO-administration-A phase I study: G-DISCO (ANZUP 2403)

ASCO GU 2025
14 FEB 2025

SUB-urothelial DURvalumab-zirconium to investigatE local and systemic distribution of durvalumab when injected in the sub-urothelium: SUBDUE-3 (ANZUP 2402)

ASCO GU 2025
14 FEB 2025

Estimating Treatment Effects After a Positive Initial Interim Analysis: Challenges and Considerations

ENZAMET
ACTA 2024
03 DEC 2024

Association of the lipid biomarker, PCPro, and clinical outcomes in the ENZAMET trial (ANZUP 1304)

ENZAMET
ESMO 2024
16 SEP 2024

Clinical prognostic factors within the high volume (HV) subgroup of metastatic hormone sensitive prostate cancer (mHSPC) in ENZAMET (ANZUP 1304)

ENZAMET
16 SEP 2024

Circulating tumour DNA fraction as a predictor of treatment efficacy in a randomized phase 2 trial of [¹⁷⁷Lu]Lu-PSMA-617 (LuPSMA) versus cabazitaxel in metastatic castration-resistant prostate cancer (mCRPC) progressing after docetaxel (TheraP ANZUP 1603)

TheraP
03 JUN 2024

PSA at 7 months is prognostic in metastatic hormone-sensitive prostate cancer (mHSPC) treated with enzalutamide: landmark analysis of ENZAMET (ANZUP 1304)

ENZAMET
03 JUN 2024

Financial Report

2024-2025



Annual Financial Report – 31 March 2025

Contents

Director’s report. 63-66

Auditor’s independence declaration 67

Financial statements

 Statement of financial position 68

 Statement of profit or loss and other comprehensive income. 69

 Statement of Changes in Funds 70

 Statement of Cash Flows 71

 Notes to the Financial Statements 72-81

 Directors’ Declaration 82

 Directors’ Declaration under the Charitable Fundraising
 Act Auditor’s Independence Declaration 83

 Independent Auditor’s Report 84-86

General information

The financial statements cover ANZUP Cancer Trials Group Limited as an individual entity. The financial statements are presented in Australian dollars, which is ANZUP Cancer Trials Group Limited’s functional and presentation currency.

ANZUP Cancer Trials Group Limited is a not-for-profit unlisted public company limited by guarantee.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 18 June 2025.



The Directors of the ANZUP Cancer Trials Group Limited (the company) presents the financial report on the period ended 31 March 2025 and report as follows:

Directors

The names of and other information on the Directors in office during or since the end of the year are as follows. The Directors were in office for this entire period unless otherwise stated.



Professor Ian Davis

Director (Chair)

Professor Ian Davis is a medical oncologist and is Professor of Medicine and Head of the Eastern Health Clinical School, Monash University and Eastern Health, in Melbourne, Australia. He has honorary appointments as an Affiliate Professor of Deakin University, adjunct Associate Professor of the University of Melbourne, Associate of the University of Sydney, Honorary Professorial Fellow with The George Institute, and Adjunct Professor of University of New South Wales. His primary clinical interests are in urologic cancers, and his primary research interests are in cancer immunology and the biology of urologic cancers. Prof Davis is chair of the ANZUP Board and of its Scientific Advisory Committee



Mr Joe Esposito

Director (Deputy Chair)

Mr Joe Esposito is a Melbourne based Director who has established a business consultancy practice, Grumentum Capital Pty Ltd. For 8 years, until 2020, he owned and operated a BOQ (Bank of Queensland) branch in the inner-city suburb of Collingwood. He has had over 20 years' experience in corporate banking in Australia and New Zealand. Between 2003 and 2006 he was the CEO of ASX listed Jetset Travelworld Limited. Mr Esposito has a close affinity with the objectives of ANZUP and the needs of cancer consumers. His qualifications include a Bachelor of Commerce, a Master of Applied Finance and a Diploma in Finance and Mortgage Management. He is a graduate member of the Australian Institute of Company Directors.



Dr Nick Buchan

Director (Chair)

Dr Nick Buchan is a Urologist based in Christchurch, New Zealand and works in both public and private practice.

Dr Buchan's practice focuses on the diagnosis and management of urological cancers. He gained his experience in medical trials while on fellowship at the Vancouver Prostate Centre. The Vancouver Prostate Centre is one of the largest research and clinical centres in the world that focuses on translational research into prostatic diseases, prostate cancer in particular. Currently Dr Buchan is Managing Director of the Canterbury Urology Research Trust (CURT). CURT is a trust that conducts urological trials for contract research organisations (CROs) as well as its own investigator lead trials in urological conditions with the focus being urological oncology. Dr Buchan is also a previous Director of a privately owned hospital in Christchurch, Forte Health and managing director of a large Urology specialist practice, Urology Associates.



Mr Martin Dowling

Director

Mr Martin Dowling has held executive and senior management level financial

and commercial roles at market leading companies in their respective industries. He has delivered in leadership roles against a broad portfolio of responsibilities across a range of industries including mining, mining services, manufacturing, and engineering. He has a Bachelor of Commerce and MBA degree and is a Fellow of CPA Australia and a graduate member of the Australian Institute of Company Directors. He is committed to the pursuit of charitable and societal goals as a Director on not-for-profit boards and also actively in the local community.



Mr Glenn Ferguson AM

Director

An experienced lawyer, he has acted in complex disputes and transactions for a range of clients both nationally and internationally. As a business and corporate lawyer, he is highly regarded for his expertise, knowledge, and professionalism in the areas of commercialisation, governance, intellectual property, mergers and acquisitions, regulatory issues and structuring advice. He is an accomplished negotiator and mediator. He is a past president of the Law Council of Australia, the peak national body which represents the legal profession nationally and internationally, past president of LAWASIA, the Law association for Asia and the Pacific and a past president of the Queensland Law Society. He is also a senior counsellor with the Queensland Law Society and an adjunct professor of law.

He is a Founding Fellow of the Australian Academy of Law, a Fellow of the Australian Institute of Company Directors, a Fellow of the Australia and New Zealand College of Notaries and a Fellow of the College of Law. He is chair of Lexon Insurance and a governor of the college of law. He is a former chair of WorkCover Queensland, a member of the federal attorney general's international legal services advisory council and the immigration minister's advisory board. The Queensland premier selected him in 2004 to Chair Smart Exports Queensland. He has been appointed by both Federal and State Governments to various advisory boards and task forces in the business, legal and migration sectors.

Glenn has also held and continues to hold a number of board positions in both the public and private sector in the insurance, superannuation, education, sport, charity and information technology areas including chairing a publicly listed company. He has a strong commitment to not-for-profit boards and provides significant pro bono assistance to a range of charities and organisations in this sector. In 2010 he was appointed by the Prime Minister to the expert panel to consider the recognition of Aboriginal and Torres Strait Islanders in the constitution.

The report was delivered in January 2012, and he continues as a member of a reference group appointed by the Minister to continue the push for constitutional recognition.

In the 2015 Australia Day Honours, Glenn was made a Member of the Order of Australia "For significant service to the law and to the legal profession, both nationally and in the Asia-Pacific region, and to the community".



Professor Henry Woo

Director

Professor Henry Woo is a urological surgeon who subspecialises in prostate disease. He is the Director of Uro-Oncology and Head of Robotic Cancer Surgery at the Chris O'Brien Lifehouse. He is also an Honorary Professor at the College of Health and Medicine of the Australian National University and Conjoint Professor in the Blacktown Mount Druitt Clinical School of Western Sydney University.

Additionally, he is the Head of the Department of Urology, at Blacktown Hospital in the Western Sydney Local Health District.

He has published widely in major urological journals. He is an Associate Editor of the Société Internationale d'Urologie Journal and serves on the journal editorial boards of World Journal of Urology, Prostate Cancer and Prostatic Diseases, Prostate International, Asian Journal of Urology and World Journal of Men's Health. He is a Fellowship elected Councillor (Board Director) of the Royal Australasian College of Surgeons and has recently been appointed Chair of the Professional Standards Committee. He also serves on the board of the charitable Australian Urological Foundation (AUF).



Professor Shomik Sengupta

Director

Shomik Sengupta is Professor of Surgery and deputy Head of School at the Eastern Health Clinical School, Monash University and consultant urology Visiting Medical Officer and Uro-Oncology lead at the Department of Urology, Eastern Health. Shomik has a practice with a uro-oncology subspecialty interest – including open, laparoscopic and robotic cancer surgery. He completed his urological training through the Victorian Section of the Urological Society of Australia & New Zealand (USANZ) and subsequently completed a Uro-Oncology fellowship at the Mayo Clinic, USA. He has also completed a Masters in Surgery (2002) and a Doctorate in Medicine (2014) through the University of Melbourne.

Shomik is a key opinion leader in Australian Urology and a strong contributor to USANZ, having been Chair of the Victorian training subcommittee from 2014 to 2016, and leader of the GU Oncology advisory group from 2013 to 2019.

His international profile has included co-opted membership of the UAA Board as deputy-director of research, USANZ representative on the Education Council of SIU, Membership of the International Bladder Cancer Group and Executive Committee membership of the World Urological Oncology Federation

Shomik has a strong interest in urologic research, including involvement in clinical trials through the Australian and New Zealand Urogenital & Prostate (ANZUP) cancer trials group, where he is a member of the Board and the Scientific Advisory Committee. Shomik has more than 165 original publications to date and has been an invited speaker/session chair at a number of scientific meetings. His involvement in leadership of scientific meetings includes current membership of the Scientific program committee for the Societe Internationale d'Urologie (SIU) 2025 Annual Congress and having been Scientific Co-chair of the Urological Association of Asia (UAA) 2022 Annual congress, Scientific Program Director for the 2017 USANZ Annual Scientific Meeting and Convenor of the 2013 ANZUP Annual Scientific Meeting. Shomik is also on the editorial board of multiple journals including the ANZ Journal of surgery, Translational Andrology and Urology, BMC Urology etc.



Professor Lisa Horvath

Director

Professor Lisa Horvath is the Director of Research and Chief Clinical Officer at the Chris O'Brien Lifehouse. She completed medical school at the University of Sydney and trained in medical oncology at Royal Prince Alfred Hospital, where she was appointed to the senior staff in 2003. She completed her PhD in translational research at the Garvan Institute of Medical Research in 2004. Professor Horvath's research interest is predominantly in the field of prostate cancer in particular biomarkers, prostate cancer biology and clinical trials. She holds academic appointments at both the University of Sydney and the University of New South Wales and is the Head of the Clinical Prostate Cancer research group at the Garvan Institute of Medical Research. Professor Horvath is the Conjoint Chair of Medical Oncology (Genitourinary Cancers) at Chris O'Brien Lifehouse. She has published more than 170 original research papers in peer-reviewed journals in the last 20+ years. She has presented extensively at national and international meetings both peer-reviewed and invited presentations. Professor Horvath is an elected ANZUP Board Director, a member of the ANZUP Scientific Advisory Committee and is Chair of the ANZUP Prostate Subcommittee.



Ms Darragh Shine

Company Secretary

Darragh is an experienced Assistant Company Secretary who has six years' experience working as a company secretary, three of which years working with global investment funds in a top law firm in Dublin, Ireland, including pension funds and insurance companies. Darragh moved to Australia and has been working with BoardRoom since July 2022. She provides corporate secretarial services to companies across a range of industry sectors, including financial services, digital tech, pharmaceutical, universities and not-for-profit organisations.

Darragh has a detailed knowledge of regulatory requirements, including ASIC, as well as best practices in Corporate Governance.

Darragh has a Bachelor of Law degree and a LLM Masters in Law from Dublin City University, as well as a Graduate Diploma in Corporate Governance and Management from University of Ulster, Ireland.

Principal activity

The principal activity of the company is to improve the lives of people affected by bladder, kidney, testicular, penile and prostate cancers through practice-changing multidisciplinary collaborative clinical trials.

There were no significant changes in the nature of the principal activities during the year.

Operating Result

The net result of the company for the financial year after providing for income tax was a surplus of \$1,068,267 (2024: surplus \$402,121). The company is a not-for-profit entity and is exempt from the payment of income tax.

Company Objectives

The objectives of the company are to develop, foster and promote prostate and urogenital cancer research by:

- Bringing together clinicians, scientists and consumers to identify critical areas of unmet need that can be addressed
- Through research in Australia and New Zealand
- Providing a collaborative forum to generate research ideas and concepts that address critical clinical questions
- Providing services and resources to support and fund research of the highest quality
- Promoting access to clinical trials for all people affected by urogenital cancers in Australia and New Zealand
- Mentoring and building the skills of future research leaders
- Securing government, industry and philanthropic funding to facilitate our independent research agenda
- Promoting our research goals and progress to improve clinical practice and change lives

The company intends to meet these objectives through performing industry sponsored and other clinical trials, ensuring these trials are widely accessible to patients, creating strong links with Cancer Australia and other peak bodies, engaging professional disciplines at all levels of protocol development and implementation, and securing funding to support clinical research training positions.

Future Developments

Likely developments in the operations of the company and the expected result of those operations in future financial years have not been included in this report as the inclusion of such information is likely to result in unreasonable prejudice to the company.

Indemnification of Officers and Auditors

The company has paid premiums to insure each director against liabilities for costs and expenses incurred by them in defending any legal proceedings arising out of their conduct involving a wilful breach of duty in relation to the company. The amount of the premium paid during the period was \$3,764.57.

After Balance Date Events

No matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the company, the results of those operations, or the state of affairs of the company in future financial years.

Meetings of Directors

The number of meetings each Director was eligible to attend and actually attended during the financial year is summarised as follows:

Limitation of Members' Liability

The company is registered under the Australian Charities and Not-for-profits Commission Act 2012 as a company limited by guarantee. If the company is wound up, its Constitution states that each member is required to contribute a maximum of \$50 each towards meeting any outstanding obligations of the company. At 31 March 2025 the number of members was 2,523 and their collective liability was \$126,150.

Directors' meetings		
	Number eligible to attend	Number attended
Ian Davis	4	4
Joe Esposito	4	4
Nicholas Buchan	4	4
Martin Dowling	4	3
Glenn Ferguson AM	4	2
Henry Woo	4	2
Shomik Sengupta	4	4
Lisa Horvath	4	3

Auditor's Independence Declaration

The auditors' independence declaration for the year ended 31 March 2025 has been received and can be found on the following page.

Signed in accordance with a resolution of the Board of Directors:



Ian Davis
Chair
Sydney, 18 June 2025



StewartBrown

Integrity + Quality + Clarity

CHARTERED ACCOUNTANTS

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ANZUP CANCER TRIALS GROUP LIMITED

ABN 32 133 634 956

FINANCIAL REPORT - 31 MARCH 2025

AUDITOR'S INDEPENDENCE DECLARATION UNDER s60-40
OF THE AUSTRALIAN CHARITIES AND NOT-FOR-PROFITS COMMISSION ACT 2012
TO THE DIRECTORS OF ANZUP CANCER TRIALS GROUP LIMITED

I declare that, to the best of my knowledge and belief, during the year ended 31 March 2025 there has been:

- (a) no contraventions of the auditor independence requirements as set out in the *Australian Charities and Not-for-profits Commission Act 2012* in relation to the audit; and
- (b) no contraventions of any applicable code of professional conduct in relation to the audit.

StewartBrown

StewartBrown
Chartered Accountants

Justin Weiner
Partner

18 June 2025

ANZUP Cancer Trials Group Limited
Statement of financial position
as at 31 March 2025

	Note	2025 \$	2024 \$
ASSETS			
Current assets			
Cash and cash equivalents	6	4,539,831	4,130,184
Trade and other receivables	7	2,707,697	1,140,803
<i>Total current assets</i>		<u>7,247,528</u>	<u>5,270,987</u>
Non-current assets			
Financial assets	8	13,347,505	12,879,702
Property, plant and equipment	9	21,894	11,139
<i>Total non-current assets</i>		<u>13,369,399</u>	<u>12,890,841</u>
TOTAL ASSETS		<u>20,616,927</u>	<u>18,161,828</u>
LIABILITIES			
Current liabilities			
Trade and other payables	10	10,449,982	9,110,461
Employee benefits	11	114,684	65,478
<i>Total current liabilities</i>		<u>10,564,666</u>	<u>9,175,939</u>
Non-current liabilities			
Employee benefits	11	14,867	12,879
<i>Total non-current liabilities</i>		<u>14,867</u>	<u>12,879</u>
TOTAL LIABILITIES		<u>10,579,533</u>	<u>9,188,818</u>
NET ASSETS		<u><u>10,037,394</u></u>	<u><u>8,973,010</u></u>
FUNDS			
Accumulated funds		9,572,354	8,504,087
Reserves		<u>465,040</u>	<u>468,923</u>
TOTAL FUNDS		<u><u>10,037,394</u></u>	<u><u>8,973,010</u></u>

The Accompanying notes form part of these financial statements

ANZUP Cancer Trials Group Limited
Statement of profit or loss and other comprehensive income
for the year ended 31 March 2025

	Note	2025 \$	2024 \$
Revenue	4	7,373,095	7,607,528
Other income	4	842,678	558,487
		<u>8,215,773</u>	<u>8,166,015</u>
Expenses			
Administration expenses		(2,288,803)	(2,339,580)
Depreciation and amortisation	5	(10,804)	(13,965)
Employee benefits expense		(2,039,044)	(1,726,153)
Finance costs	5	-	(1,036)
Grant funding - Below The Belt Grants		(177,273)	(25,000)
Grant funding - other		(2,628,015)	(3,656,236)
Other expenses		(3,567)	(1,924)
		<u>(7,147,506)</u>	<u>(7,763,894)</u>
Surplus before income tax		1,068,267	402,121
Income tax expense		<u>-</u>	<u>-</u>
Surplus for the year		1,068,267	402,121
Other comprehensive income			
<i>Items that may be reclassified subsequently to profit or loss</i>			
Fair value gain (loss) on financial assets		(3,883)	351,997
Other comprehensive income for the year		<u>(3,883)</u>	<u>351,997</u>
Total comprehensive income for the year		<u><u>1,064,384</u></u>	<u><u>754,118</u></u>

The Accompanying notes form part of these financial statements

ANZUP Cancer Trials Group Limited
Statement of changes in funds
for the year ended 31 March 2025

	Accumulated Funds	Financial Assets Reserve	Total
	\$	\$	\$
Balance at 1 April 2023	8,101,966	116,926	8,218,892
Comprehensive income			
Surplus for the year	402,121	-	402,121
Other comprehensive income	-	351,997	351,997
Total comprehensive income for the year	<u>402,121</u>	<u>351,997</u>	<u>754,118</u>
Balance at 31 March 2024	<u>8,504,087</u>	<u>468,923</u>	<u>8,973,010</u>
Balance at 1 April 2024	8,504,087	468,923	8,973,010
Comprehensive income			
Surplus for the year	1,068,267	-	1,068,267
Other comprehensive income	-	(3,883)	(3,883)
Total comprehensive income for the year	<u>1,068,267</u>	<u>(3,883)</u>	<u>1,064,384</u>
Balance at 31 March 2025	<u>9,572,354</u>	<u>465,040</u>	<u>10,037,394</u>

The Accompanying notes form part of these financial statements

ANZUP Cancer Trials Group Limited
Statement of cash flows
for the year ended 31 March 2025

	Note	2025 \$	2024 \$
Cash flows from operating activities			
Receipts from customers and government		263,822	1,636,531
Payments to suppliers and employees		(7,708,330)	(8,915,164)
Donations, legacies and fundraising receipts		126,116	386,497
Grants received		7,387,079	7,217,574
Interest received		837,772	520,138
Interest paid - leases		-	(1,036)
<i>Net cash flows from operating activities</i>		<u>906,459</u>	<u>844,540</u>
Cash flows from investing activities			
Purchase of property, plant and equipment		(25,126)	(12,709)
Purchase of financial assets		(471,686)	(1,569,005)
<i>Net cash flows from investing activities</i>		<u>(496,812)</u>	<u>(1,581,714)</u>
Cash flows from financing activities			
Repayment of lease liabilities		-	(7,315)
<i>Net cash flows from financing activities</i>		<u>-</u>	<u>(7,315)</u>
Net increase (decrease) in cash and cash equivalents		409,647	(744,489)
Cash and cash equivalents at the beginning of the financial year		<u>4,130,184</u>	<u>4,874,673</u>
Cash and cash equivalents at the end of the financial year	6	<u><u>4,539,831</u></u>	<u><u>4,130,184</u></u>

The Accompanying notes form part of these financial statements

Note 1 - Corporate information

The financial report includes the financial statements and notes of ANZUP Cancer Trials Group Limited ('the company'). ANZUP Cancer Trials Group Limited is registered as a company limited by guarantee and not having a share capital under the provisions of the *Australian Charities and Not-for-profits Commission Act 2012*.

ANZUP is a multidisciplinary cancer cooperative trials group that conducts clinical trial research to improve treatment of bladder, kidney, testicular, penile and prostate cancers. The company continues to strengthen its trials portfolio, build membership base, improve communications, enhance the activities of the company's committees and subcommittees, develop new resources and opportunities for members, and to ensure financial viability for current and projected future activities.

The registered address and principal place of business of the company is:

Tower 3, Level 18
300 Barangaroo Avenue
Barangaroo NSW 2000

The financial statements were approved by the Board of Directors on 18 June 2025.

Note 2 - Basis of preparation

Statement of compliance

These general purpose financial statements have been prepared in compliance with the requirements of the *Australian Charities and Not-for-profits Commission Act 2012* and *Australian Accounting Standards - Simplified Disclosures*. The company is a not-for-profit entity for the purposes of preparing these financial statements.

Basis of measurement

The financial statements, except for the cash flow information, have been prepared on an accruals basis and are based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities.

Comparatives

Where required by Accounting Standards or to achieve consistency in financial statements presentation, the prior year financial comparatives have been adjusted to conform with current year disclosures and allow comparison with current financial year disclosures.

Critical accounting estimates and judgements

The Directors evaluate estimates and judgements incorporated into the financial statements based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the company.

Key estimates

Impairment - general

The Directors assess impairment at the end of each reporting period by evaluation of conditions and events specific to the company that may be indicative of impairment triggers. Recoverable amounts of relevant assets are reassessed using value-in-use calculations which incorporate various key assumptions.

Estimation of useful lives of assets

The estimation of the useful lives of assets has been based on historical experience as well as manufacturers' warranties (for plant and equipment) and turnover policies (for motor vehicles). In addition, the condition of the assets is assessed at least once per year and considered against the remaining useful life. Adjustments to useful lives are made when considered necessary.

Note 2 - Basis of preparation (continued)

New and revised standards that are effective for these financial statements

Several amendments and clarifications to Australian Accounting Standards and interpretations are mandatory for the 31 March 2025 reporting period. These include:

- AASB 2020-1, AASB 2022-6 and AASB 2023-3: *Amendments to AASB 101 – Classification of Liabilities as Current or Non-current*
- AASB 2023-1: *Amendments to AASB 7 and 107 – Supplier Finance Arrangements*
- AASB 2024-1: *Amendments to AASB 1060 – Supplier Finance Arrangements: Tier 2 Disclosures*

The application of these amendments and clarifications have not had a material impact on the carrying values of the company's asset, liability or equity balances; nor a material impact on the disclosures in the financial report nor the recognition and measurement of the company's revenue or expenses.

New standards and interpretations not yet adopted

Certain new accounting standards, amendments and interpretations have been published that are not mandatory for 31 March 2025 reporting periods and have not been early adopted by the company. These include:

- AASB 18 – *Presentation and Disclosure in Financial Statements* (applicable for the year ending 31 March 2028)
- AASB S1 – *General Requirements for Disclosure of Sustainability-related Financial Information* (applicable for the year ending 31 March 2026, depending on criteria qualification outcomes)
- AASB S2 – *Climate-related Disclosures* (applicable for the year ending 31 March 2026, depending on criteria qualification outcomes)

It is not expected that AASB 18, AASB S1 or AASB S2 will have a material impact on the company in future reporting periods. AASB S1 and AASB S2 will only have mandatory application to entities required to report under Chapter 2M of the *Corporations Act 2001* for annual reporting periods commencing on or after 1 July 2025. The company is currently assessing whether there will be any material change to disclosures in financial reporting in future years as a consequence of sustainability reporting requirements. As at the date of this financial report AASB S1 and AASB S2 do not have mandatory application to the company as the company prepares its financial report under the *Australian Charities and Not-for-profits Commission Act 2012* financial reporting framework.

Note 3 - Accounting policies

The material accounting policies adopted in the preparation of the financial report are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

Goods and services tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Taxation Office (ATO).

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the ATO is included with other receivables or payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to, the ATO are presented as operating cash flows included in receipts from customers or payments to suppliers.

Income tax

ANZUP Cancer Trials Group Limited is a not-for-profit exempt institution from income tax under Division 50 of the *Income Tax Assessment Act 1997*. The company has deductible gift recipient (DGR) status.

Note 3 - Accounting policies (continued)

Revenue recognition

Amounts disclosed as revenue are net of returns, trade allowances and duties and taxes including goods and services tax (GST). Revenue is recognised for the major business activities as follows:

Conference income

Annual Scientific Meeting (ASM) conference revenue is recognised during the year in which the event takes place. The company contracts a professional events co-ordinator to manage the staging of the ASM conference including the receipt of revenue and payment of expenses in relation to the event.

Distributions from managed funds

Revenue from distributions from managed funds is recognised on an accruals basis.

Donations

Income arising from the contribution of an asset (including cash) is recognised when the following conditions have been satisfied:

- a) the company obtains control of the contribution or the right to receive the contribution;
- b) it is probable that the economic benefits comprising the contribution will flow to the company; and
- c) the amount of the contribution can be measured reliably at the fair value of the consideration received.

Grants

Revenue from government and pharmaceutical grants are recognised as revenue when the company obtains control over the asset comprising the contributions. The company does not have control of the contribution or does not have the right to receive the contribution or has not fulfilled grant conditions, the grant contribution is treated as deferred income.

Interest

Interest revenue is recognised as it accrues using the effective interest method.

Sponsorship revenue

Sponsorship revenue is recognised over the period to which the sponsorship relates.

Other revenue

Other revenue is recognised as revenue on an accruals basis.

Cash and cash equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash, and which are subject to an insignificant risk of changes in value and bank overdrafts.

Trade receivables

For all sources of recurrent income, trade receivables are recognised initially at fair value and subsequently measured at amortised cost, less provision for doubtful debts. Collectability of trade receivables is reviewed on an ongoing basis. Debts which are known to be uncollectible are written off. A provision for impairment is established when there is objective evidence that the company will not be able to collect all amounts due according to the original terms of receivables.

The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the effective interest rate. The amount of the provision is recognised in the statement of profit or loss and other comprehensive income.

Note 3 - Accounting policies (continued)

Property, plant and equipment

Recognition and measurement

Each class of property, plant and equipment is carried at cost less, where applicable, any accumulated depreciation and impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. Purchased software that is integral to the functionality of the related equipment is capitalised as part of that equipment. Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in the statement of comprehensive income.

Subsequent costs

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the company and the cost of the item can be measured reliably.

Carrying Amount

The carrying amount of property, plant and equipment is reviewed annually by the Directors to ensure that it is not in excess of the recoverable amount from those assets. The recoverable amount is assessed on the basis of the expected net cash flows that will be received from the assets' employment and subsequent disposal. The expected net cash flows have been discounted to their present values in determining recoverable amounts.

Depreciation

The depreciable amount of all property, plant and equipment and capital works in progress, is depreciated on a straight line basis over the asset's useful life to the company commencing from the time the asset is held ready for use.

The depreciation rates used for each class of depreciable assets are:

Office equipment	33%
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The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Financial instruments

Initial recognition and measurement

Financial assets and financial liabilities are recognised when the company becomes a party to the contractual provisions to the instrument. For financial assets this is equivalent to the date that the company commits itself to either purchase or sell the asset. Financial instruments are initially measured at fair value plus transactions costs except where the instrument is classified "at fair value through profit or loss" in which case transaction costs are expensed to profit or loss immediately. Trade receivables are initially measured at the transaction price if the trade receivables do not contain a significant financing component.

Classification and subsequent measurement

Financial assets

Financial assets other than those designated and effective as hedging instruments are classified upon initial recognition into the following categories:

- Amortised cost
- Equity instruments at fair value through other comprehensive income (FVOCI)
- Fair value through profit or loss (FVPL)

All income and expenses relating to financial assets that are recognised in profit or loss are presented within finance income or finance costs, except for impairment of trade receivables which are disclosed with other expenses.

Note 3 - Accounting policies (continued)

Financial instruments (continued)

Measurement is on the basis of two primary criteria:

- The contractual cash flow characteristics of the financial asset
- The business model for managing the financial asset

Financial assets at amortised cost

Financial assets are measured at amortised cost if the asset meets the following conditions (and are not designated as FVPL):

- The financial asset is managed solely to collect contractual cash flows
- The contractual terms within the financial asset give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding on specified dates

Equity instruments at fair value through other comprehensive income

Investments in equity instruments that are not held for trading are eligible for an irrevocable election at inception to be measured at fair value through other comprehensive income. Subsequent movements in fair value are recognised in other comprehensive income and are never reclassified to profit or loss. Dividend revenue received on underlying equity instruments investment will still be recognised in profit or loss unless the dividend clearly represents return of capital. By default, all other financial assets that do not meet the measurement conditions of amortised cost and fair value through other comprehensive income are subsequently measured at fair value through profit or loss.

Financial assets at fair value through profit or loss

Financial assets that are held within a different business model other than to “hold and collect” or “hold to collect and sell” are categorised at fair value through profit or loss. The initial designation of financial instruments to measure at fair value through profit or loss is a one-time option on initial classification and is irrevocable until the financial asset is derecognised.

Impairment of financial assets

The impairment requirements as applicable under AASB 9 use more forward-looking information to recognise expected credit losses. Expected credit losses are the probability-weighted estimate of credit losses over the expected life of a financial instrument. A credit loss is the difference between all contractual cash flows that are due, and all cash flows expected to be received, all discounted at the original effective interest rate of the financial instrument.

The Directors considers a broad range of information when assessing credit risk and measuring expected credit losses, including past events, current conditions, reasonable and supportable forecasts that affect the expected collectability of the future cash flows of the instrument. In applying this approach, a distinction is made between:

- Financial instruments that have not deteriorated significantly in credit quality since initial recognition or that have low credit risk
- Financial instruments that have deteriorated significantly in credit quality since initial recognition and the credit risk is not low
- Financial assets that have objective evidence of impairment at reporting date

The loss allowance for the first category is measured as “12-month expected credit loss” and for the second category is measured as “lifetime expected credit losses”.

Note 3 - Accounting policies (continued)

Impairment of assets

Assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash generating units). Impairment losses are reversed when there is an indication that the impairment loss may no longer exist and there has been a change in the estimate used to determine the recoverable amount.

Trade and other payables

Trade and other payables represent the liability outstanding at the end of the reporting period for goods and services received by the company during the reporting period, which remain unpaid. The balance is recognised as a current liability with the amounts normally paid within 30 days of recognition of the liability. The carrying amount of trade and other payables is deemed to reflect fair value.

Income received in advance

Income, other than government contract income, that is received before the service to which the payment relates has been provided is recorded as a liability until such time as the service has been provided, at which time it is recognised in the statement of comprehensive income.

Employee benefits

Short-term employee benefits

Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled wholly within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

Other long-term employee benefits

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are measured at the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on high quality corporate bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

Fair value of assets and liabilities

The company measures some of its assets and liabilities at fair value on either a recurring or non-recurring basis, depending on the requirements of the applicable Accounting Standard. Fair value is the price the company would receive to sell an asset or would have to pay to transfer a liability in an orderly (ie unforced) transaction between independent, knowledgeable and willing market participants at the measurement date.

As fair value is a market-based measure, the closest equivalent observable market pricing information is used to determine fair value. Adjustments to market values may be made having regard to the characteristics of the specific asset or liability. The fair values of assets and liabilities that are not traded in an active market are determined using one or more valuation techniques. These valuation techniques maximise, to the extent possible, the use of observable market data.

To the extent possible, market information is extracted from either the principal market for the asset or liability (ie the market with the greatest volume and level of activity for the asset or liability) or, in the absence of such a market, the most advantageous market available to the company at the end of the reporting period (ie the market that maximises the receipts from the sale of the asset or minimises the payments made to transfer the liability, after taking into account transaction costs and transport costs).

Note 3 - Accounting policies (continued)

Fair value of assets and liabilities (continued)

For non-financial assets, the fair value measurement also takes into account a market participant's ability to use the asset in its highest and best use or to sell it to another market participant that would use the asset in its highest and best use.

The fair value of liabilities and the company's own equity instruments (excluding those related to share-based payment arrangements) may be valued, where there is no observable market price in relation to the transfer of such financial instruments, by reference to observable market information where such instruments are held as assets. Where this information is not available, other valuation techniques are adopted and, where significant, are detailed in the respective note to the financial statements.

Foreign currency transactions and balances

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the year-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined.



	2025 \$	2024 \$
Note 4 - Revenue and other income		
Revenue		
Grant income	5,854,498	5,823,302
Donations	126,116	386,497
Honorariums	14,276	9,477
Corporate Supporter Program	286,250	78,750
Sponsorship	148,500	445,500
Annual Scientific Meeting	943,455	864,002
<i>Total revenue</i>	<u>7,373,095</u>	<u>7,607,528</u>
Other income		
Interest income	326,789	47,397
Investment income	511,463	472,741
Sundry income	4,426	38,349
<i>Total other income</i>	<u>842,678</u>	<u>558,487</u>
<i>Total revenue and other income</i>	<u>8,215,773</u>	<u>8,166,015</u>
Note 5 - Expenses		
Depreciation and amortisation		
Property, plant and equipment	10,804	8,505
Right-of-use assets	-	5,460
<i>Total depreciation and amortisation</i>	<u>10,804</u>	<u>13,965</u>
Finance costs - lease liability	-	1,036
Net loss on disposal of property, plant and equipment	3,567	-
Note 6 - Cash and cash equivalents		
Cash at bank	1,480,402	4,130,184
Term deposits	3,059,429	-
<i>Total cash and cash equivalents</i>	<u>4,539,831</u>	<u>4,130,184</u>
Note 7 - Trade and other receivables		
Current		
Trade receivables	2,356,748	861,329
Other receivables	68,555	68,075
Prepayments	282,394	211,399
<i>Total current trade and other receivables</i>	<u>2,707,697</u>	<u>1,140,803</u>
Note 8 - Financial assets		
Non-current		
Managed investments	13,347,505	12,879,702
<i>Total non-current financial assets</i>	<u>13,347,505</u>	<u>12,879,702</u>
Movements in carrying amount		
Opening net carrying amount	12,879,702	10,958,700
Additions	471,686	1,569,005
Fair value gain (loss)	(3,883)	351,997
Closing net carrying amount	<u>13,347,505</u>	<u>12,879,702</u>

	2025 \$	2024 \$
<u>Note 9 - Property, plant and equipment</u>		
Office equipment - at cost	29,472	57,420
Accumulated depreciation	(7,578)	(46,281)
<i>Net carrying amount</i>	<u>21,894</u>	<u>11,139</u>
<u>Movements in carrying amounts</u>		
Opening net carrying amount	11,139	6,935
Additions	25,126	12,709
Disposals	(3,567)	-
Depreciation charge for the year	(10,804)	(8,505)
Closing net carrying amount	<u>21,894</u>	<u>11,139</u>
<u>Note 10 - Trade and other payables</u>		
<u>Current</u>		
Trade payables	199,217	453,960
Income in advance	9,865,760	8,333,179
Other payables	385,005	323,322
<i>Total current trade and other payables</i>	<u>10,449,982</u>	<u>9,110,461</u>
<u>Note 11 - Employee benefits</u>		
<u>Current</u>		
Annual leave	103,206	65,478
Long service leave	11,478	-
<i>Total current employee benefits</i>	<u>114,684</u>	<u>65,478</u>
<u>Non-current</u>		
Long service leave	14,867	12,879
<i>Total non-current employee benefits</i>	<u>14,867</u>	<u>12,879</u>
<u>Note 12 - Key management personnel</u>		
<u>Remuneration of key management personnel</u>		
The aggregate amount of compensation paid to key personnel during the year was:	<u>261,420</u>	<u>365,475</u>
<u>Note 13 - Auditor's remuneration</u>		
Fees paid to StewartBrown, Chartered Accountants:		
Audit of the financial report	16,000	15,000
Preparation of the financial report	5,200	5,000
<i>Total auditor's remuneration</i>	<u>21,200</u>	<u>20,000</u>
<u>Note 14 - Related party transactions</u>		
During the year, the company received honorariums of \$14,276 (2024: \$9,457). These honorariums were in relation to speaking engagements undertaken by Ian Davis.		
<u>Note 15 - Limitation of members' liability</u>		
The company is incorporated as a company limited by guarantee, and in accordance with the constitution the liability of members in the event of the company being wound up would not exceed \$50 per member. At 31 March 2025 the number of members of this company was 2,523 (2024: 2,387).		

Note 16 - Commitments

Research grants

Commitments contracted for at the reporting date, but not recognised as liabilities are as follows:

	2025 \$	2024 \$
Within one year	10,474,784	8,527,931
Later than one year but not later than five years	1,826,034	3,454,937
	<u>12,300,818</u>	<u>11,982,868</u>

Contingent liabilities and capital

The company has no contingent liabilities or capital commitments as at year end (2024: Nil).

Note 17 - Charitable fundraising activities

(a) Fundraising income and expenditure

Gross proceeds from fundraising	126,116	386,498
Total costs of fundraising	142,627	185,365
Net surplus (deficit) from fundraising	<u>(16,511)</u>	<u>201,133</u>

(b) Key fundraising ratios

Total cost of fundraising (A)	142,627	185,365
Gross proceeds from fundraising (B)	126,116	386,498
(A) divided by (B)	113%	48%
Net surplus (deficit) from fundraising (A)	(16,511)	201,133
Gross proceeds from fundraising (B)	126,116	386,498
(A) divided by (B)	-13%	52%

(c) Fundraising income activities

Income is mainly derived from general fundraising activities and Pedalthon fundraising event.

(d) Expenditure of funds raised

All funds derived were applied towards achieving ANZUP's charitable objectives.

(e) Directors' Declaration

Made in accordance with a resolution of the Directors under the New South Wales *Charitable Fundraising Act 1991*.

Note 18 - Events occurring after balance date

There were no significant events occurring after balance date.

DIRECTORS' DECLARATION

The Directors of ANZUP Cancer Trials Group Limited declare that:

1. The financial statements, which comprises the statement of financial position as at 31 March 2025, and the statement of profit or loss and other comprehensive income, statement of changes in funds and statement of cash flows for the year ended on that date, and notes to the financial statements, including material accounting policy information, are in accordance with the *Australian Charities and Not-for-profits Commission Act 2012* and:
 - (a) comply with *Australian Accounting Standards - Simplified Disclosures* (including Australian Accounting Interpretations) and the *Australian Charities and Not-for-profits Commission Regulations 2022*; and
 - (b) give a true and fair view of the financial position of the company as at 31 March 2025 and of its performance for the year ended on that date.
2. In the opinion of the Directors, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.



Ian Davis
Chair

Sydney, 18 June 2025

DIRECTORS' DECLARATION
UNDER THE CHARITABLE FUNDRAISING ACT 1991

In the opinion of the Directors of ANZUP Cancer Trials Group Limited:

- (i) The financial statements and notes thereto give a true and fair view of all income and expenditure with respect to fundraising appeals conducted by the company for the year ended 31 March 2025;
- (ii) The statement of financial position as at 31 March 2025 gives a true and fair view of the state of affairs of the company with respect to fundraising appeals conducted by the company;
- (iii) The provisions of the *Charitable Fundraising Act 1991*, the regulations under that Act, and the conditions attached to the authority to fundraise have been complied with by the company; and
- (iv) The internal controls exercised by the company are appropriate and effective in accounting for all income received and applied by the company from any of its fundraising appeals.

This declaration is made in accordance with a resolution of the Board of Directors.



Ian Davis
Chair

Sydney, 18 June 2025



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CHARTERED ACCOUNTANTS

**INDEPENDENT AUDITOR'S REPORT TO THE DIRECTORS OF
ANZUP CANCER TRIALS GROUP LIMITED**

Opinion

We have audited the financial report of ANZUP Cancer Trials Group Limited which comprises the statement of financial position as at 31 March 2025, the statement of profit or loss and other comprehensive income, the statement of changes in funds and statement of cash flows for the year then ended, and notes to the financial statements, including material accounting policy information, and the Directors' Declaration.

In our opinion, the accompanying financial report of ANZUP Cancer Trials Group Limited is in accordance with the *Australian Charities and Not-for-profits Commission Act 2012*, including:

- a) giving a true and fair view of the company's financial position as at 31 March 2025 and of its financial performance for the year then ended, and
- b) complying with *Australian Accounting Standards - Simplified Disclosures* and the *Australian Charities and Not-for-profits Commission Regulations 2022*.

Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibility for the Audit of the Financial Report* section of our report. We are independent of the company in accordance with the auditor independence requirements of the *Australian Charities and Not-for-profits Commission Act 2012* and the ethical requirements of the Accounting Professional and Ethical Standards Board's *APES 110 Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Australian Charities and Not-for-profits Commission Act 2012*, which has been given to the Directors of the company, would be in the same terms if given to the Directors as at the time of this auditor's report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Directors' Responsibility for the Financial Report

The Directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with *Australian Accounting Standards - Simplified Disclosures* and the *Australian Charities and Not-for-profits Commission Act 2012* and for such internal control as the Directors determine is necessary to enable the preparation of a financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

The Directors are responsible for overseeing the company's financial reporting process.

Liability limited by a scheme approved under Professional Standards Legislation

INDEPENDENT AUDITOR'S REPORT TO THE DIRECTORS OF
ANZUP CANCER TRIALS GROUP LIMITED

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at *The Auditing and Assurance Standards Board* and the website address is <http://www.auasb.gov.au/Home.aspx>

We communicate with the Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Report on Charitable Fundraising Regulations and Requirements

We have audited the financial report as required by Section 24 of the New South Wales *Charitable Fundraising Act 1991*. Our procedures included obtaining an understanding of the internal control structure for fundraising appeal activities and examination, on a test basis, of evidence supporting compliance with the accounting and associated record keeping requirements for fundraising appeal activities pursuant to the New South Wales *Charitable Fundraising Act 1991* and the New South Wales *Charitable Fundraising Regulations 2021*.

Because of the inherent limitations of any assurance engagement, it is possible that fraud, error or non-compliance may occur and not be detected. An audit is not designed to detect all instances of non-compliance with the requirements described in the above-mentioned Act and Regulations as an audit is not performed continuously throughout the period and the audit procedures performed in respect of compliance with these requirements are undertaken on a test basis. The audit opinion expressed in this report has been formed on the above basis.

INDEPENDENT AUDITOR'S REPORT TO THE DIRECTORS OF
ANZUP CANCER TRIALS GROUP LIMITED

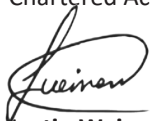
Opinion

In our opinion:

- a) The financial report of the company has been properly drawn up and associated records have been properly kept during the financial year ended 31 March 2025, in all material respects, in accordance with:
 - i. Sections 20(1), 22(1-2), 24(1) of the New South Wales *Charitable Fundraising Act 1991*; and
 - ii. Section 17 of the New South Wales *Charitable Fundraising Regulations 2021*.
- b) The money received as a result of fundraising appeals conducted by the company during the financial year ended 31 March 2025 has been properly accounted for and applied, in all material respects, in accordance with the above-mentioned Act and Regulations.



StewartBrown
Chartered Accountants



Justin Weiner
Partner

18 June 2025

Partners, Corporate and In-kind Supporters

Corporate Supporters

We are grateful for the invaluable support of our corporate partners, whose contributions empower ANZUP to better support our members and, ultimately, improve outcomes for patients and their families.



In-Kind Supporters

We sincerely appreciate the generosity of the following organisation for providing their services in support of our mission.



We also express our sincere appreciation to the SAC, CAP, Subcommittees, ASM Convening Committee, and all our members for their dedicated service.



ANZUP Cancer Trials Group Limited

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