What a difference a few months makes!

We held our first 2020 Annual Scientific Meeting (ASM) convening committee meeting in July 2019 where we decided on our theme, “Clear Vision”— recognising that we are working in a time of rapid development in all areas of cancer medicine. Then came COVID-19 and suddenly we were catapulted into seeing first-hand what a “rapidly evolving health and medical research system” really looks like. While we planned for a tsunami, implementing contingencies in order to maintain productivity, we also needed to ensure the health, safety and wellbeing of the patients, health care professionals, and other staff involved in patient care and research remained paramount. We have seen remarkable collaborations and innovations emerge, eg. alcohol distilleries making hand sanitisers, repurposing 3D printers to develop much needed personal protective equipment, rapid deployment of digitally enabled telehealth, as well as our pharmaceutical partners working closely with us to ensure supply of drugs to patients’ homes. As restrictions begin to lift the question remains for us all, what will our new normal look like?

Despite COVID-19, we have continued to hit some significant milestones!

We activated DASL-HiCaP (ANZUP 1801) and recruited our first patient on 30 April. This study aims to recruit 1,100 patients from over 100 sites across Australia, New Zealand, US, Canada, UK and Ireland. DASL is a collaboration between ANZUP and our friends and colleagues at the Canadian Cancer Trials Group, Dana-Farber Cancer Institute, Prostate Cancer Clinical Trials Consortium and Cancer Trials Ireland. The University of Sydney's NHMRC Clinical Trials Centre will act as the central coordinating centre.

Congratulations to Chris Sweeney, Tamim Niazi and the DASL trial team of investigators, site staff and coordinating centres on this achievement.

We were delighted to announce our TheraP trial (ANZUP 1603) will feature as an oral presentation in the ASCO 2020 virtual meeting on Friday 29 May, with Michael Hofman presenting the interim results. TheraP is the first randomised trial comparing $^{177}$Lu-PSMA-617 (Lu-PSMA), a novel radioactive treatment, to the current standard-of-care chemotherapy called cabazitaxel for men with metastatic castration-resistant prostate cancer. TheraP is a partnership between ANZUP and the Prostate Cancer Foundation of Australia (PCFA) with support from the Australian Nuclear Science and Technology Organisation (ANSTO), Endocyte, It’s a Bloke Thing, Movember, CAN4CANCER and the University of Sydney’s NHMRC Clinical Trials Centre provided central study coordination. We are very grateful to all the investigators, trial coordinators and patients and their families for their participation.

Our soon to be launched ENZAp trial (ANZUP 1901) is an ANZUP-led randomised phase II trial using PSMA as a therapeutic agent (Lutetium -PSMA) and prognostic indicator (PSMA-PET) in men with metastatic castrate-resistant prostate cancer treated with enzalutamide. This study is being led by Louise Emmett from St Vincent’s Hospital in Sydney. The study aims to recruit 160 patients, across 12 sites.

#UpFrontPSMA, (ANZUP co-badged) trial is a randomised phase 2 study of sequential $^{177}$Lu-PSMA-617 and docetaxel versus docetaxel in metastatic hormone-naïve prostate cancer, also randomised its first patient. Congratulations to Arun Azad and Michael Hofman and the entire UpFront team on this achievement.

Both ENZAp and UpFrontPSMA received funding from the Prostate Cancer Research Alliance (PCRA): An Australian Government and Movember Foundation Collaboration.

We recently held our first two virtual Concept Development Workshops (CDW) where 14 concepts were presented to our multidisciplinary members. It was great to see how engaged our members stayed using Zoom. We are planning to call for new concepts for Germ Cell, Renal Cell, Quality of Life and Translational later in the year. The CDWs are a way of ensuring a pipeline of innovative ideas can be considered and prioritised, with potential support from the Below the Belt Research Fund, over the next 12 months.
ANZUP partnered with COSA and MDBriefCase to develop an online education module discussing the Advances in therapy for patients with renal cell carcinoma. You can access the program here.

While there was further disappointment, and a few tears, with the postponement of this year’s Melbourne Pedalthon, we continue to be overwhelmed by the generosity of the ANZUP community. We are extremely grateful to our friends at the Melbourne Racing Club Foundation and Sandown who have kindly agreed to transfer our March booking to a date later in the year, hopefully November. A big thank you to all our riders, donors and sponsors for your understanding and your continued support.

Our Sydney Pedalthon in September will also be postponed, however we are working on an exciting virtual challenge which will be launched in the near future. The challenge will be open to all our members, supporters and the general public around Australia and New Zealand, and will not only appeal to the cycling enthusiasts but also for those who enjoy walking and running, and with your friends, family, colleagues or by yourself. All in the name of raising awareness and funds for our clinical trials research and keeping us all fit and healthy.

Due to overwhelming support from our members, I am pleased to announce we will be holding a mini-ASM in November in Melbourne. The program is currently being finalised however in brief, it will feature the MDT Masterclass, an evening symposium, Best of GU highlights as well as a conference dinner. We will be announcing more details over the coming weeks as we firm up the program.

Sadly, earlier this year Guy Toner announced he would be standing down from the ANZUP Board at the AGM in July. Guy was pivotal in the initial establishment of ANZUP, having for many years chaired one of its predecessor organisations, ANZGCTG. Guy has been a director and deputy chair since ANZUP’s inception, and through this time has guided the organisation to where it is today. He has been the quiet but effective force behind many of our initiatives, including the highly successful Below the Belt Research Fund and more recently the Discretionary Funding Initiative. Guy’s wise advice and mentorship has positively influenced clinicians and researchers all over the world. We are planning a celebration at our “mini ASM” in November in order to recognise in some small way the enormous contribution he has made both to ANZUP and the global GU oncology community.

Finally, we will be holding our Annual General Meeting (AGM) on Monday 20 July. With Guy planning to stand down, we have called for nominations to fill his position. If the number of candidates is equal to or less than the number of vacancies, the Board may appoint the candidates on the appointment date without holding a ballot. However if a ballot is required, I will email the list of candidates to members at least 20 days before the AGM. The vote on any nominations for director will occur at the AGM on Monday 20 July, 2020.

Thank you for all you have done and all you continue to do.

Please stay well.

Warmest regards,

MARGARET MCJANNETT
CEO, ANZUP
MESSAGE FROM THE CHAIR

Welcome to the first edition of UPdate for 2020. UPdate is the newsletter of the Australian & New Zealand Urogenital and Prostate Cancer Trials Group Ltd (ANZUP).

2019 was a tumultuous year. On the one hand, we in ANZUP had the amazing high of the positive outcomes from ENZAMET, with the ASCO Plenary presentation and our simultaneous paper in NEJM. That was then followed by the presentation of the quality of life data at ESMO by Martin Stockler; plans to extend follow-up of the study; FDA approval of enzalutamide for this indication, in December 2019; and then naming by ASCO of ENZAMET as one of its Clinical Cancer Advances for 2020, in the ASCO Annual Report on Progress Against Cancer, published in J Clin Oncol at https://ascopubs.org/doi/10.1200/JCO.19.03141 on World Cancer Day, February 4, 2020. We are in the process of nominating ENZAMET for the Australian Clinical Trials Alliance Trial of the Year award. We completed recruitment to UNiSoN and TheraP, and we are pleased that TheraP will be an oral presentation at ASCO 2020.

On the other hand, all of us were affected directly or indirectly by the devastating bushfires that destroyed the environment and the lives of so many people. The fires lasted for months, and their effects will last for lifetimes. We saw stories of heartbreak, but we also saw the most noble and heartwarming evidence of humanity at its very best.

After all that I think we came into 2020 a little bit exhausted. We are often caught up in our bubbles of work, family, interests; and for many of us ANZUP is a big part of all of those. 2020 was to be our year of consolidation, taking stock of where we are and where we are going, and looking ahead to a future without limits and with renewed energy. Our year was already planned out, with the Annual Scientific Meeting planning well advanced, dates for our concept development workshops, the Below the Belt Pedalthons continuing to build momentum, and planning underway for many other educational and group activities. What theme could we have chosen for our Annual Scientific Meeting in the year 2020 that would be more appropriate than “Clear Vision?”

Well, it’s now late in May as I write this, and we seem to be living in a very strange world. At the beginning of the crisis I think it was the uncertainty that was the worst: when and how will COVID-19 affect us? Will our systems be able to cope? What will be asked of me? What is the risk to my patients, my colleagues, myself, and to those I love literally more than life itself? What can I possibly do to make a difference? Now we are almost through this first wave, but we know it has not gone away and there is still the possibility of later waves of the pandemic, with all that that would mean. These concerns will be overwhelming for some people, and I hope that you know how to find the help and support you need if that describes you.

The answer to all of that is similar to what we give to our patients. It’s too much to take in when you consider it as a whole. “How do you eat an elephant? One bite at a time.” We must break it down into achievable tasks. Let’s accept that usual routines won’t be possible. We might have to reprioritise tasks. We might have to take on new ones, and offload others to other people. We wait for the next set of updated guidelines, and meanwhile we chip away at the bits over which we have some control. We need to change how we do things, and sometimes those are the hardest – I am struggling not to touch my face right now even as I have both hands on the keyboard, and by the way where is the cleaning solution for the keyboard? Today the ANZUP team have set up systems so that they can continue their important work from home rather than in the ANZUP offices at LifeHouse. My health service is transforming its model of care in anticipation of what we hope will not happen. We are as prepared as we can be, not knowing what is coming, but with confidence in those around us and in the strength of our teams.

And then it occurred to me. Our patients must feel like this All The Time. I had a distressed patient on a ward...
round and I told him that I understood (do I, really?), and that it is all much easier from my side of the bed than his. We put together a plan, in bite-sized and achievable chunks. We changed what we were doing. We transformed our model of care. We grew confidence in the team we had assembled. And, strangely, something else happened: we consolidated, took stock, looked ahead to a future that arguably did have some limits, but also had renewed energy. We planned the next sets of activities. I hope, although I cannot be entirely sure, that by the time we left the bedside we had shared some “Clear Vision,” and I’m pretty sure I saw some of humanity at its very best.

You will know by now that ANZUP has had to make some difficult decisions. We have postponed the 2020 ASM and moved everything to 18-20 July 2021, in Adelaide, with the same fantastic convening committee led by Nick Brook, and commitment from everyone from the convention centre to the invited international speakers that they will be there for us then. We have deferred the Melbourne Pedalthon and hope to run it later in the year. We are running our Concept Development Workshops remotely. Our other events are all under similar consideration.

Our clinical trials continue, but we recognise that adjustments will need to be made there too. There have been effects on trial recruitment, site activation, participant review and follow-up, with resultant protocol deviations. Some trials have had to be deferred; some might not end up going ahead. We are working closely with sites to help them mitigate all of these issues, but we are also all very much aware how much need there is for us to continue to provide the care our patients require, and that our clinical trials are a key component of that. It’s not all bad news though: COVID-19 did not stop us opening the international DASL-HiCaP trial!

All of the world’s current events will of course adversely affect ANZUP’s financial situation. The good news is that we are well prepared for this. Marg McJannett as our CEO, and the ANZUP Board, have managed ANZUP finances very carefully so that we could continue to operate even if our funding disappeared entirely. We are able to continue to do what we need to do, including ongoing support for the Below the Belt Research Fund: watch out for more news on this soon. ANZUP continues to rely on fundraising and we will continue to ask you to think of ways you can support the organisation, including raising awareness in the professional and broader community and with philanthropy.

I usually start writing this newsletter by looking back over what we said in the last one. This piece has an ever so slightly different tone to my previous ones…! But as you chew each elephant bite 32 times before swallowing, think about this: we were small, but we have already changed the world of GU oncology and transformed the lives of thousands of people. Together we are much greater than the sums of our parts, although each of those parts is pretty great. There is still work to do to help those we serve, even though there seem to be a lot of distractions around at the moment.

And each little act of kindness and love increases the amount that the world has to share, and like Certain Viruses, these acts spread widely and end up having effects many of us might never have predicted.

Look after yourselves and stay safe. Keep doing what you do (except the bits you shouldn’t be doing!) We’ve heard about #SocialDistancing, but perhaps we need to think of it more as #SpatialDistancing while we maintain #SocialConnections. What we do collectively is still very important, and it will not stop just because we keep a bit more distance, and wash our hands, and otherwise need to change things we never thought we would have to change. We’ve changed the world before: let’s keep doing that.

ANZUP and all of its parts is strong and healthy. There is a lot to celebrate and a lot to share. And yes, I think we see ourselves and our patients more clearly in this ocular year of 2020. Please enjoy this edition of UPdate.

IAN DAVIS
ANZUP Chair
ANZUP’s ENZAMET trial results recognised as one of the most important clinical research advances of the past year

On World Cancer Day, Tuesday 4 February 2020, the American Society of Clinical Oncology, Inc. (ASCO) released its Clinical Cancer Advances 2020: ASCO’s Annual Report on Progress Against Cancer. This report highlights the most important clinical research advances of the past year and identifies priority areas where ASCO believes research efforts should be focused moving forward.

ANZUP’s ENZAMET study, “Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer,” has been selected for inclusion in this year’s edition.

The landmark Australian led clinical trial, ENZAMET, showed that hormone therapy with a drug called enzalutamide can improve the survival of some men with advanced, hormone-sensitive prostate cancer.

Findings from the ENZAMET trial, led by ANZUP, showed that men with this sort of cancer who receive enzalutamide with standard treatment have a 33% improvement in survival compared to men receiving standard treatment alone.

ANZUP Chair, Professor Ian Davis, said metastatic prostate cancer was still the second-leading cause of cancer death in Australian men after lung cancer.

“The benefits of enzalutamide had already been established for prostate cancers that are no longer responding to hormonal therapy. ENZAMET showed that adding enzalutamide to standard treatment for men starting hormonal therapy for prostate cancer led to a 33% reduction in the chance of dying of prostate cancer, and a 60% improvement in the time it takes to detect the cancer growing again. These results were much better than we thought they might be when we started the trial.

Prostate cancer is complex and so are the benefits, side effects and risks of multiple treatments.

Clinical trials are the most effective way of determining which treatments, alone or in combination, will provide the greatest survival benefit to the patient with the least adverse outcomes.”

Professor Christopher Sweeney, co-chair with Professor Ian Davis of the ENZAMET trial, said, “Inclusion in ASCO’s Annual Report is testament to the fact that this is one of the most significant findings yet in clinical trials for men with metastatic hormone-sensitive prostate cancer – and a great example of effective international collaboration.”
ANZUP was fortunate to have five trials in progress at ASCO GU in San Francisco in February.

Congratulations to everyone involved in these important ANZUP studies.

**PCR-MIB (ANZUP 1502) Study**
Chair Andrew Weickhardt presented the poster on pembrolizumab with chemoradiotherapy as treatment for muscle invasive bladder cancer: a planned interim analysis of safety and efficacy of the PCR-MIB phase II clinical trial.

**ANZUP Fellow Shahlini Subramaniam** presented the **P3BEP (ANZUP 1302) poster**: an international randomised phase III trial of accelerated versus standard BEP chemotherapy for adult and pediatric male and female patients with intermediate and poor-risk metastatic germ cell tumors (GCTs).

**ANZUP Fellow Elizabeth Liow** presented the **BCGMM (ANZUP 1301) poster**: adding mitomycin to Bacillus Calmette-Guérin as adjuvant intravesical therapy for high-risk, non muscle-invasive urothelial bladder cancer.
DASL-HiCaP (ANZUP 1801)
Study Co-Chair Tamim Niazi presented the DASL-HiCaP poster: the impact of darolutamide on standard therapy for localised very high-risk cancer of the prostate – 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.

UNISoN (ANZUP 1602)
Study Chair Craig Gedye presented the UNISoN poster: nivolumab then ipilimumab + nivolumab in advanced non-clear cell renal cell carcinoma.

As an ANZUP fellow, I truly valued the opportunity of being involved with ANZUP’s UNISoN trial. UNISoN is an important trial that focuses on patients with non-clear cell kidney cancer, and may expand the treatment armamentarium for a group of patients who do not have access to many effective treatment options. I for one eagerly anticipate the results from the UNISoN trial.

Elizabeth Liow
DASL-HiCaP sees first patient enrolled in Sydney

The first of 1,100 patients has been enrolled on a new cancer trial for treatment for men with high risk, clinically localised prostate cancer.

The DASL-HiCaP trial, led by ANZUP, enrolled its first patient at Chris O’Brien Lifehouse in Camperdown in Sydney in April 2020.

The new randomised phase 3 study aims to demonstrate that the addition of the new potent oral hormonal therapy, darolutamide, to the standard radiation therapy and testosterone suppression improves the outcomes of men with localised high-risk prostate cancer.

Outcomes of the trial will be measured in terms of whether the addition of darolutamide decreases the risk of spreads of prostate cancer to other parts of the body as well as improving quality of life and potentially decrease the risk of prostate cancer death.

“We know clinical trials are the only way to find out the safety and effectiveness of new treatments and whether they should become the new gold standard for treatment in the future,” said ANZUP Chair, Professor Ian Davis.

The first patient enrolled marks the start of the journey to recruit and follow up 1,100 eligible patients across over 100 cancer centres across Australia, New Zealand, US, Canada, Europe and Ireland. The trial is being led by ANZUP in collaboration with the NHMRC Clinical Trials Centre, as the global coordinating centre, Dana Farber Cancer Institute, the Prostate Cancer Clinical Trials Consortium US, Cancer Trials Ireland and the Canadian Cancer Trials Group.

Study Co-Chairs Associate Professor Tamim Niazi and Professor Christopher Sweeney are excited with the potential this trial has for patients.

“DASL-HiCaP is specifically designed to assess whether the potent hormone treatment can lessen the risk of recurrence of prostate cancer in men who demonstrate a high risk of the cancer spreading to other parts of the body. The patients in this study will be men treated with testosterone suppression along with radiation, or radiation after surgery, and who are at significant risk of the cancer relapsing. Our hope is that this trial might show new ways of improving outcomes for these men with prostate cancer,” said Professor Sweeney.

Investigator Meeting

The Investigator Meeting was held in Sydney on Friday 31 January 2020. We had close to 100 people attend from across Australia, New Zealand, Ireland and the US.

The meeting provided the background and rationale of the trial; gave a detailed overview of the management of the protocol including treatment schedules, study visits, safety reporting and timelines.
International Standards for the Analysis of Quality of Life and Patient Reported Outcomes Endpoints in Cancer Randomised Controlled Trials


Patient-reported outcome (PRO) data, such as symptoms, functioning and other health-related quality of life endpoints are often included in cancer randomised controlled trials (RCTs) to provide valuable evidence on risks, benefits, safety and tolerability of treatment. PRO findings can and should inform patients, providers, payers and regulatory decision-makers. Ideally, PRO findings would be analysed, interpreted and reported in ways that are both easily understood and methodologically appropriate and robust. However, in reality, the opposite is true - PRO data are analysed with a confusing array of methods and presented and interpreted in many different ways. Standards and clear guidelines are needed.

The SISAQOL Consortium - Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data – is setting this straight.

This paper reports the first set of consensus recommendations for PRO analysis in cancer RCTs. These address four key priorities:

1) A taxonomy of PRO objectives for RCTs
2) Appropriate statistical methods for each PRO objective type
3) Standardised statistical terminology for missing PRO data
4) Appropriate ways to manage missing data

This represents an important first step towards generating international consensus-based standards for PRO analysis in cancer RCTs.
ANZUP remains committed to running our trials. Challenges may arise from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial participants become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures however the safety of the patient and of our researchers is paramount.

We will continue to monitor the situation, and work with the Study Chairs, sites, coordinating centres and study drug providers in order to support you during this time. We are developing some practical guidance to inform and support your local conduct of our ANZUP-led trials.

Please reach out to us if there is anything further ANZUP can do to assist you or your site.

**ANZUP led studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Study sites</th>
<th>Recruitment</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BCG MM (ANZUP 1301)</strong></td>
<td>13 sites</td>
<td>266 patients randomised</td>
<td>500 patients</td>
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<tr>
<td><strong>PCR MIB (ANZUP 1502)</strong></td>
<td>6 sites open in Australia.</td>
<td>20 patients</td>
<td>30 patients</td>
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<tr>
<td><strong>DASL-HiCaP (ANZUP 1801)</strong></td>
<td>100 anticipated</td>
<td>3 patients</td>
<td>1,100 patients across Australia, New Zealand, US, Canada, UK and Ireland</td>
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<tr>
<td><strong>P3BEP (ANZUP 1302)</strong></td>
<td>42 sites open 19 (ANZ), 10 (UK) and 13 (US)</td>
<td>123 patients randomised</td>
<td>500 patients</td>
</tr>
<tr>
<td><strong>KEYPAD (ANZUP 1601)</strong></td>
<td>14 sites</td>
<td>37 patients</td>
<td>70 patients</td>
</tr>
<tr>
<td><strong>TIGER (ANZUP 1604)</strong></td>
<td>4 sites</td>
<td>5 patients randomised</td>
<td>420 patients internationally and 60 ANZ</td>
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</table>
ANZUP led studies (continued)

**UNICAB (ANZUP 1802)**
- **Study sites**: 11 sites, 1 satellite site at Shepparton
- **Recruitment**: 11 patients
- **Target**: 48 patients

**#UpFrontPSMA**
- **Study sites**: 12 sites
- **Recruitment**: 1 patient
- **Target**: 140 patients

**NINJA (TROG 18.01)**
- **Study sites**: 10 sites are anticipated to participate across Australia. Currently 3 sites are open
- **Recruitment**: 49 patients

**ENZA-p (ANZUP 1903)**
- **Study sites**: 12 sites
- **Recruitment**: 0
- **Target**: 160 patients

**NMIBC-SI Evaluation**
- **Study sites**: 17 sites
- **Recruitment**: Patients enrolled field test 1: 220 (closed - completed)
  Patients enrolled field test 2: 248

ANZUP Co-badged studies

**ANZUP led study soon to open**
While telehealth has existed in Australia for some time, it’s entirely possible many patients and caregivers hadn’t heard about it until the COVID-19 outbreak when the government announced a new telehealth program as part of its response to ‘flatten the curve’.

Rural communities have had access to telehealth for a while – but when COVID-19 led to increased social distancing and isolation measures, there was a need to expand the offering.

Telehealth allows people to access essential health services in their home while they undergo self-isolation or quarantine and it reduces the risk of exposure to COVID-19 for vulnerable people in the community.

In addition, telehealth is a way of delivering health services remotely, either through telephone, video conferencing or other forms of communication technologies. It allows health services to be brought to patients who are unable to be in physical contact with a health service provider and the consultation can be done on various platforms such as FaceTime, a phone and Skype.

Teletrials builds on the telehealth model and increases access to clinical trials for people with cancer living in rural and remote locations, or in isolation due to COVID-19. Teletrials also allows trial recruitment and activity to continue and expand.

ANZUP is embarking on its first tele-trial with the UNICAB trial. The primary site, Border Medical Oncology, under the guidance of Dr Craig Underhill will work with the satellite site investigator Dr Javier Torres, Goulburn Valley, Shepparton. Led by Study PI David Pook, UNICAB is a phase II trial aiming to find how safe, tolerable and effective a new treatment called cabozantinib is for non-clear cell kidney cancer.

Dr Craig Underhill said, “Regional cancer patients experience several disadvantages including lower survival rates, due to healthcare access differentials...

a Teletrials Program aims to reduce the barriers for regional patients with cancer to access clinical trials, including travel, cost and social disruption.”

What is a teletrial?

A teletrial allows a clinician at a larger centre (primary site) to enrol, consent and treat patients on clinical trials in collaboration with smaller regional and rural centres (satellite sites), allowing patients to participate closer to home, and during COVID-19 isolation.

Participation in clinical trials is recommended as the best option for many cancer patients. The teletrial model means access to novel, ground-breaking treatments for everyone no matter where they are based – in isolation, regional, rural and remote areas.

Medical oncologists and trial coordinators from primary trial sites can use teleoncology to help obtain consent, recruit, treat and monitor patients at satellite sites, and at home, during routine or trial-specific consultations depending on the type of study. And just as with face-to-face clinical trials, teletrials also takes into consideration the requirements for proper conduct to ensure the trials are both safe and ethical.

Will telehealth and teletrials continue to grow?

Telehealth has already expanded in response to the COVID-19 crisis so it is sure to become more widely accepted and even easier to use in the future. There is no reason why telehealth tools won’t become an integral part of healthcare systems worldwide and digital health is a quickly developing tool for regional patients’ access to health services. ANZUP hopes the success of the UNICAB teletrial will help the health service challenge of meeting recruitment targets and bring cancer treatments and trial participation to the broader community.
The ANZUP Scientific Advisory Committee (SAC) met by teleconference on 11 March 2020. These meetings generally go for about two hours (I blame the Chair), and it was very interesting once again that about 80% of that time was taken up in strategic discussion rather than detailed accounts of individual studies. SAC oversight of each of our trials remains very important, but the SAC’s main function is to provide advice and strategic scientific direction for ANZUP overall. We discussed our strategic plan; governance processes; links with other organisations; funding opportunities including grants; ratified decisions made by the SAC executive on time-critical matters; debated teletrial possibilities; considered processes in the light of the postponed ASM and previously-planned workshops; and reviewed issues relevant to each discipline and each subcommittee.

The SAC regularly reviews its membership, with a view to maintaining broad-based multidisciplinary representation. Members are appointed by the Board on the recommendation of relevant special societies or other organisations. I would particularly like to acknowledge three people at this time:

- Martin Stockler, who has been deputy chair of the SAC almost since its inception. Martin has always contributed tirelessly to ANZUP in many capacities, and has now stood down from his deputy role although he continues to provide epidemiology expertise, as well as medical oncology.

- Scott Williams, who was the foundation chair of the Prostate subcommittee. Scott is stepping down as chair and we will begin processes for replacement of the chair and (if necessary) deputy chair positions. Scott has also contributed enormously to ANZUP’s success with his strategic, scientific, and clinical input, and as PI on several studies. Scott will now take up the role of SAC deputy chair.

- Pam Russell has represented the broader scientific community on the SAC since it began, but many people might not know the extent of what Pam has contributed to ANZUP. Pam was instrumental in establishing the organisation before it existed, when the-then “Australian Prostate & Urogenital Cancer Group (APUG)” was formed and later joined with the Australia & New Zealand Germ Cell Trials Group (ANZGCTG) in 2008 to form ANZUP. Pam was a member of the original Board of Management of APUG and its secretary, and was a founding director of ANZUP when it was established. Pam saw ANZUP through its formative years of evolution, including some difficult times, and did so with grace, wisdom, dedication, and humour. I vividly remember the planning meeting where she came up with a fundraising strategy of “Balls for balls,” which much to my regret never went ahead although its distant descendant, our prizewinning “Rude Food” social media campaign, was wildly successful. Pam is known internationally as a towering figure in prostate cancer scientific research, having previously worked in autoimmune disease: of course she was awarded an AM in 2003, and of course she warrants her own Wikipedia page. Pam has had to step down from her ANZUP SAC role but we will forever be grateful to her for what she has done for us and for so many other people.

As a consequence of Pam standing down we have written to the Australian Society of Medical Research (ASMR) and am pleased to announce Dr Lisa Butler has been nominated. We look forward to welcoming Lisa onto the SAC at the next virtual meeting on Monday 20 July.

Thanks as always to the members of the SAC, its subcommittees, the Consumer Advisory Panel, and the Board for its support.

All ANZUP members are reminded that you are welcome to participate in any of the subcommittees at whatever level you wish. If you are not currently on a subcommittee mailing list and you wish to be, please let me or the ANZUP secretariat know so that we can add you.

IAN DAVIS
Chair, ANZUP Scientific Advisory Committee
ANZUP Cancer Trials Group acknowledges the past several months have seen significant changes made by institutions so they can manage COVID-19. This has and will continue to have an impact on usual trial operations - but some Bladder, Urothelial and Penile cancer trials are progressing and we would like to take this opportunity to provide an update on current activity and additional developments.

In May I was interviewed by Norman Swan’s ABC Health Report on the Shortage of key treatment for bladder cancer. You can listen to the podcast here.

Highlights include:

- The BCG-mitomycin study, comparing sequential BCG & Mitomycin to standard BCG for high-risk non-muscle invasive bladder cancer (NMIBC), has recruited steadily and has 264 patients of a planned 500 patients accrued.
- The UK site and two more sites in Australia (including Nepean) are to open shortly.
- There are currently global BCG and mitomycin shortages, which are causing problems and the management of patients very difficult. In addition, there is an issue with mitomycin not dissolving easily in 40ml of normal saline.
- The PCR-MIB study was temporarily suspended in March 2020. Up until that point, the 21st patient (of 30) was screened and recruited to the study. I am pleased to report that recruitment has now recommenced.
- An interim analysis was conducted that showed no new safety concerns and an abstract was submitted to GU ASCO based on pre-designed stopping rules.

A number of potential future studies are at various stages of development and/or discussion:

ACCEPT multicentre cystectomy database is collecting data from West Australian centres, with ethics and governance review underway to open at other sites interstate. It is hoped this database will not only provide a much-needed audit of cystectomy practices but also enable implementation and evaluation of interventions such as Enhanced Recovery pathways.

- The South Metro Health Service Human Research Ethics Committee (HREC) in WA is now the lead HREC for the national mutual acceptance process. Therefore, all public hospitals now have ethics approval. Each site will require governance approval.
- Due to the low-risk nature of the study, waiver of consent has been obtained for retrospective and prospective data collection (rather than the opt-out consent previously required).
- We would like to thank Cynthia Hawks, from the Fiona Stanley Hospital, for completely redoing the entire ethics approval process to make it easier to open centres. This should result in a large, multi-centre audit.

Water irrigation for low/intermediate risk NMIBC is a Below the Belt funded single centre pilot study, with plans for a subsequent ANZUP trial to compare it to post-resection chemotherapy.

- Patients are being enrolled on a 30-patient, single-arm pilot ‘WATIP’ study. Patients are given a trans urethral resection of bladder tumour (TURBT) or bladder endoscopic treatment followed by 3 hours of post-operative water irrigation.
- To date, 19 patients out of a total of 30 patients have been recruited. It is hoped the remaining 11 patients will accrue over the next 3-6 months, however elective surgery has been impacted by COVID-19.
- So far the procedure has been feasible and no safety issues have been found. Samples have been collected from study patients together with samples from standard saline-irrigated patients. It has been found...
Bladder, Urothelial and Penile Cancer (BUP)

there are fewer numbers of viable cells in the water-irrigated samples compared to the saline-irrigated cells, at each time point.

- A grant application for a randomised trial was unsuccessful last year, however the application is being amended to include this latest data and will be resubmitted this year.

- The Exercyst Trial: Exercise Medicine Prior to Open Radical Cystectomy: Feasibility and Preliminary Efficacy: 14/20 patients have been recruited to this single-arm exercise study. To date, 10 patients have completed the study. Recruitment should hopefully be completed by the end of 2020. The study is progressing well.

- In addition, Exercyst 2 is being developed. It will be a post-operative exercise trial with dose escalations, looking at the feasibility and safety of immediate post-operative exercise after major abdominal surgery.

The 2019 Below the Belt grants included funding for a Phase I study of sub-urothelial injection of Durvalumab (SUBDUE-1).

This trial looks at feasibility and toxicity of a sub-urothelial injection of durvalumab as a potential new primary treatment for non-muscle invasive bladder cancer. The trial recruits patients already scheduled for cystectomy and involves administration of the drug into the bladder wall with a dose escalation protocol.

ANZUP has been heavily involved in the development of the study, which is running only at Fiona Stanley Hospital and is sponsored by South Metro Health Services. Astra Zeneca is providing durvalumab but no other support for the study. The trial is funded by a Below the Belt grant and another local grant (Spinnaker) in WA has been obtained for translational work.

The study is open and was recruiting within 12 months of the initial idea for the concept being formulated. Two patients have been recruited thus far.

Concept Submissions
ANZUP is committed to supporting our membership through the COVID-19 pandemic while continuing to promote and encourage members to bring new concepts forward to ensure protocol development.

The Concept Development Workshops (CDWs) are designed to facilitate and support members who have an idea/concept they would like to put forward for discussion and, if supported, to further develop into a future grant application.

We held our first ‘Zoom’ Concept Development Workshop on Thursday 30 April 2020. We had 4 concepts presented and over 30 people attend.

ANZUP remains committed to running clinical trials however we appreciate this has become difficult with the current challenges - but we hope to move past recent hurdles and look forward to the progression of BUP concepts and trials and another productive year.

DICKON HAYNE & SHOMIK SENGUPTA
Chair and Deputy Chair, BUP Subcommittee
Early in 2020, the Germ Cell Subcommittee continued to be very productive, welcoming new members, including trainees, who contributed to research activity. A focus for 2020 is to get a surgical study underway and keep our fingers crossed for funding of a stage 1 study looking at microRNA and fear of cancer recurrence.

**Ongoing activity in the Germ Cell Subcommittee include:**

1. TIGER is open at multiple sites in Australia, recruiting 5 patients. This has been one of the most important studies in germ cell cancer for some time, comparing TIP versus TICE (high dose with stem cell rescue) as first salvage for platinum refractory disease.

2. iTestis is continuing to expand, opening at multiple sites across the country, now having recruited over 200 patients, but still looking for additional sites. This is a testicular cancer registry, supported by ANZUP, that hopes to engage as many sites and clinicians as possible. Please contact Ben Tran if you are interested in participating. Data collection support can be provided.

3. P3BEP continued to recruit well. 102 patients have been recruited across ANZ, UK and COG sites! Well done to Peter Grimison and team on successfully driving this study! We’re fast approaching the first interim analysis.

4. The ANZUP surveillance guidelines for both stage 1 and advanced disease (following curative chemotherapy) are now available on the ANZUP website.

In the pipeline, the following continue to be a focus for the Germ Cell Subcommittee for 2020.

1) Micro RNA analyses appear to be a promising biomarker for testicular cancer, both seminoma and non-seminoma. Ben Tran is leading an ANZUP MRFF grant, submitted in Feb 2020, which will serve as a parallel study to both SWOG 1824 and AGCT1531, two international studies which have only recently started recruiting patients. The focus will be on patients with stage 1 testicular germ cell tumours and will also assess interventions for fear of cancer recurrence.

2) Planning is underway for a surgical study for testicular germ cell tumours. The use of RPLND in stage 2 Seminoma and Recurrent Node-only Non-Seminoma has been reported by several groups internationally. We’re hoping to start an ANZUP study that will help address PROMs in this patient population.

3) Having a survivorship plan is increasingly recognised as an important component of ongoing care for testicular germ cell tumour patients. Jeremy Lewin is leading an effort in generating a clinically useful survivorship plan that can be implemented across Australia.

4) Hypogonadism is a complex issue in testicular cancer survivors. It can be a result of both primary or secondary, with secondary causes often under-appreciated and perhaps more common. Feasibility studies using iTestis are underway to determine the proportion of survivors with secondary hypogonadism. And if the population is sufficient a small pilot study using novel agents to address this will be designed.

We look forward to holding our Concept Development Workshop later in 2020.

**BEN TRAN & FRITHA HANNING**

Chair and Deputy Chair, Germ Cell Subcommittee
ANZUP & PCFA Partnership Grant

With the renewal of our Memorandum of Understanding for our PCFA ANZUP Partnership Grant for a further three years, ANZUP called for prostate cancer concepts late last year.

A number of high quality concepts were submitted and the shortlisted applicants presented their concepts to a multidisciplinary panel on Tuesday 26 November 2019. It was great to see so many creative and interesting concepts.

Congratulations to Shahneen Sandhu for her novel concept: Lutetium-PSMA with ipilimumab and nivolumab in metastatic hormone naive prostate Cancer (mHNPC). This will be the next ANZUP PCFA sponsored protocol.

ANZUP is also looking at ways to support the other submissions over the next 12 months.

So far, this year has proved to be both difficult and challenging. ANZUP however, remains committed to running urogenital clinical trials and the prostate cancer trials are still progressing with ongoing activity with new developments and achievements.

DASL-HiCaP

In April 2020, the first of 1,100 patients was enrolled in the DASL-HiCaP trial at Chris O’Brien Lifehouse. This is an ANZUP-led randomised phase 3 trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in high risk, clinically localised prostate cancer. Study Co-Chairs Associate Professor Tamim Niazi and Professor Christopher Sweeney are excited with the potential this trial has for patients.

ENZAMET

On World Cancer Day, Tuesday 4 February 2020, the American Society of Clinical Oncology, Inc. (ASCO) released its Clinical Cancer Advances 2020: ASCO’s Annual Report on Progress Against Cancer. This report highlights the most important clinical research advances of the past year and identifies priority areas where ASCO believes research efforts should be focused moving forward. ANZUP was excited as the ENZAMET study, “Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer,” was selected for inclusion in this year’s edition.

In addition, an International Trials Steering Committee has been established for ENZAMET translational work. This includes representatives from all regions with specific expertise. The Committee meets formally every six months via teleconference. A sub-group of four experts meets monthly to prioritise proposals for the use of specimens. Detailed proposals with budgets are currently being finalised for submission for funding.

ENZA-p

ENZA-p is an ANZUP-led randomised phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castrate-resistant prostate cancer treated with enzalutamide. This study is being led by Associate Professor Louise Emmett from St Vincent’s Hospital in Sydney. The study aims to recruit 160 patients, across 12 sites – with the view to open the study by mid-2020. Initially 10 sites (which have been used for TheraP) are planned to be opened for this study.

TheraP

Accrual has completed for the initial analysis of TheraP, the randomised trial of cabazitaxel chemotherapy against Lutetium-PSMA in castrate-resistant disease. An abstract was submitted to ASCO 2020, and I am pleased to announce we have been accepted to do an oral presentation at the virtual meeting in May.

Pain-Free TRUS B

The Pain-Free TRUS B randomised trial completed accrual and this study has an instantaneous endpoint. A recruitment total of 420 patients was achieved following ongoing contributions from our NZ study leaders. The analysis plan is now being discussed.
**ProPSMA**

The primary analysis for the ProPSMA study, (co-badged with ARTnet and TROG) has been completed. This study had been booked for a Plenary Session at the EAU in Amsterdam, however the EAU was cancelled due to COVID-19. It was published in the Lancet on 21 March and will be another headline study for Australia in the PSMA space.

**#UpFrontPSMA**

In April 2020 the first patient was consented at the Peter MacCallum Cancer Centre for #UpFrontPSMA. This study will be run at sites that participated in ENZA-p and it will be co-badged by ANZUP and VCCC/ the Peter MacCallum Cancer Centre.

**Concepts**

Several exciting concepts are continuing in development and Below the Belt funded studies are progressing well. In addition the concept development workshops are still being held. Over 40 people attended and 9 concepts were presented at our virtual Concept Development Workshop in May, with a view to developing a path to fully-fledged prostate cancer clinical trials. We encourage all Prostate Cancer Subcommittee members to attend this multidisciplinary educational event where a cross section of prostate cancer research concepts, from molecular biology and biomarker studies to psycho-oncology and survivorship, are discussed and analysed.

Exciting achievements and new studies continue to make sure ANZUP is well-recognised in prostate cancer clinical trial research. We encourage Prostate Subcommittee members to refer new members to support ongoing growth of this group. Even with the current climate, the year ahead will be another busy one full of ideas and activities for the prostate cancer subcommittee and ANZUP.

**SCOTT WILLIAMS & LISA HORVATH**

Chair and Deputy Chair, Prostate Cancer Subcommittee

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**Quality of Life & Supportive Care**

**Life goes on**

How much have we been through since our last UPdate? Summer fires, floods, and a global pandemic. Many of us have had to transition rapidly to online care, teaching, meetings, and socialising. It has been an interesting time adjusting to a lifestyle somewhat curtailed by the virus and the need for physical distancing – I much prefer the Irish term ‘cocooning’ to describe what we are doing. Regardless, much of our work has continued, largely uninterrupted, with transitions in trials and research protocols to incorporate telehealth follow-up. The big questions we need to answer as we emerge from our cocoons (not too soon!) are related to transforming our models of care to keep what works from both telehealth and face-to-face care to deliver better person-centred care.

**Concept development workshops**

I’d like to thank the members of our subcommittee who have been committed to attending the tumour site subcommittee meetings and the CDWs on a regular basis. Early input and engagement from those of us with a supportive care, psychosocial, and quality of life focus is critical in maximising the outcomes of ANZUP clinical trials. In addition to quality of life outcomes, we are assessing fear of cancer recurrence or anxiety and depression in other clinical trials. We are seeing an increase in discussion of patient experience during CDWs, at times data can best be collected as part of routine follow-up in the trial, while at others it requires inclusion of qualitative substudies to inform our
Quality of Life & Supportive Care continued

thinking about the problem and the experience. This is exciting for all of us, as it means we will be better placed in the future to assess for these concerns, develop and evaluate interventions, and even investigate implementation of evidence-based approaches within ANZUP’s clinical trials.

New study: Online exercise for people with metastatic prostate cancer

Holly Evans, Camille Short and team have launched their online exercise study for individuals with metastatic prostate cancer. The 8-week program involves an individually tailored exercise program, devised using the online algorithm. It also includes complementary education and telehealth support for participants. As we have seen the rapid expansion of telehealth services over the past few months – there is much to learn about how to do this safely and effectively. So this initiative from Holly and Cam is very timely. Although, I think many of us have found the process of interacting with patients remotely challenging in a number of ways.

Subcommittee Meetings

I’ve been slow to get the subcommittee meetings set up for 2020. However, we will be holding the next meeting on 5 June. This will give us a terrific opportunity to review the work being done and think about where there are gaps for us to work on and build the evidence for better care and better delivery of care. There are great opportunities for us to be partnering with the Psycho-Oncology Cooperative Trials Group (POCOG), the Cancer Symptom Trials Group (CST), and the Primary Care Collaborative Cancer Clinical Trials Group (PC4) on questions of mutual interest that may be across tumour types. POCOG and PC4 are actively working on projects investigating telehealth and other approaches to delivery of care for people with cancer and those who have completed active treatments – you may be hearing about these studies from different sources soon.

Quality of Life Office – change in Cancer Australia Performance Indicators

Marg McJannett and I recently met with the team from the Quality of Life Office (QOLO). With continued Cancer Australia (CA) funding as a technical service, the performance indicators for the QOLO have changed to reflect the focus of the CA support for the clinical trials groups in the developmental stages of the trials. Thus, we are aiming to facilitate QOLO review of ANZUP concepts prior to the CDWs. Our subcommittee is working closely with Dr Rachel Campbell, the QOLO representative for ANZUP, to make this a valuable and painless process for all. Rachel will be joining us for our meetings and CDW and for the tumour subcommittee CDWs in the future. As always ANZUP remains committed to including the most relevant outcomes for people living with GU and prostate cancer in our trials – having QOLO is having access to another great resource to help us do this.

ASM 2020 - postponed

As you are all aware, it was necessary for ANZUP to postpone the full ASM due to the COVID-19 restrictions. Sadly, this means Cristiane Decat Bergerot won’t be joining us this year. I am keen to do a video chat with Cris to talk about her psycho-oncology work, the areas of GU cancer she is working on, big questions for the future, and life as an early career researcher. If you have questions you’d like to ask Cris, please drop me a line. I am sure we all have plenty of things to share with one another and this may be a great way of doing so.

Looking forward to seeing and hearing from many of you on 5 June for our next get together. But I am very much looking forward to the time we can all be together in person to share, question, and laugh as we work on our goals to improve cancer care. Until then stay well, cocoon, and emerge only when needed.

HARYANA DHILLON & CATHERINE PATERSON
Chair and Deputy Chair, QoL and Supportive Care Subcommittee
ANZUP remains committed to running clinical trials during this difficult and challenging time. We appreciate there may be significant changes which may impact on usual trial operations. But to date, the renal cell trials are all still progressing with ongoing activity and further developments.

The UNISoN study has only a few patients remaining on part one of the trial who are soon to transition to part two. Yet again we are very grateful to the teams working on this study around Australia.

The KEYPAD study continues to recruit, but recruitment has been slow. There is evidence patients with good risk IMDC RCC no longer exist in Australia and all other patients appear to have intermediate or high risk RCC. We are now contacting referring doctors at KEYPAD sites to cross-refer patients. In addition, the possibility of opening the study in New Zealand is being explored as well as a radical change in protocol to include a new cohort of patients.

The UNICAB study is open across 11 sites in Australia with a target of 48 participants. So far recruitment has been quite slow with only 10 patients accrued and 3 in screening.

UNICAB is an exciting phase II trial of cabozantinib in patients with metastatic or unresectable non clear-cell renal cell carcinoma who have progressed on, or are not candidates for immunotherapy. As previously outlined UNICAB was also designed as a partner to the UNISoN study, as patients can be enrolled on UNICAB if they progress on UNISoN. The study also provides a treatment option for patients who have medical conditions that do not allow them to be treated with immunotherapy. UNICAB is ANZUP’s first tele-trial. Please contact us if you have an appropriate patient for this trial or would like further information on tele-trials.

The RCC Subcommittee will also hold a Concept Development Workshop in the first half of 2020 via videoconference. We encourage all RCC Subcommittee members, as well as our emerging researchers, trainees and recent graduate members, to attend as an educational opportunity, even if you are not presenting a concept.

The workshops continue to provide opportunities to brainstorm potential answers to tough clinical questions in kidney cancer research, as well as the development of paths towards fully-fledged kidney cancer trials.

We extend our thanks to Subcommittee members who have referred new members to support membership growth. We encourage you to continue referring new members - varying disciplines, trainees and different geographical locations - are all welcome.

We look forward to another productive year for the Renal Cell Cancer Subcommittee as well as the progression of renal cell trials and concepts.

CRAIG GEDYE & DAVID POOK
Chair and Deputy Chair, RCC Committee
It has been a busy few months for the Translational Research Subcommittee, with some important updates that we are excited to share.

The ENZAMET/ENZARAD Translational Research Steering Committee has overseen the selection of several key projects using correlative samples from ENZAMET. Thanks to the independent group that reviewed and prioritised proposals. We are now working on budget and logistics with a view to commencing research, albeit we expect delays due to work restrictions from the COVID-19 pandemic. The projects that will go forward will utilise cutting-edge technology to deliver critical correlative data from this pivotal, practice-changing trial. We are also very pleased that these translational studies will bring together a team of researchers from across the globe. Enhancing links with international translational researchers has been a key goal of the Translational Research Subcommittee and we are delighted that ENZAMET is providing a platform to achieve this.

Although laboratory research is our major focus, there are additional opportunities to perform sub-studies using data from ENZAMET. One example is an imaging study led by Associate Professor Anthony Joshua that will correlate PSMA PET data with clinical outcomes.

While pushing forward with the planning for ENZAMET translational studies, we will also shortly commence planning for correlative samples collected for TheraP. Results from this world-first study will be presented at the ASCO virtual meeting on 29 May. We eagerly await the chance to commence translational research from this exciting study. As with ENZAMET, we will be calling for translational proposals and expect that this will occur in the second half of 2020.

Bio-specimen collection continues as part of existing trials, including BCGMM, P3BEP, KEYPAD, UNISoN, PCR-MIB, DASL-HiCaP, ENZAMET and ENZARAD. As always, we are grateful for the patients and families who enrol on our trials and donate bio-specimens that underpin our translational research. We could not conduct our activities without these high-quality samples, and acknowledge the participating sites diligence in obtaining correlative samples from our ANZUP trials.

We look forward to another successful year ahead for the Translational Subcommittee during the remainder of 2020.

ARUN AZAD & ANTHONY JOSHUA
Chair and Deputy Chair, Translational Subcommittee

“Friends of ANZUP” is an initiative connecting people whose lives have been impacted by prostate, kidney, bladder, penile or testicular cancers.

Friends of ANZUP provides:
• Information about the benefits of clinical trials and how to access them
• Support from people who understand the challenges
• Biannual community magazine, ‘A Little Below the Belt’
• Invitation to Community Engagement Forums

Please refer consumers to “Friends of ANZUP” and help us achieve our mission to improve the outcomes and treatment for those living with prostate, kidney, bladder, penile and testicular cancers. Find out more at: http://www.anzup.org.au/friendsofanzup.aspx
We are nearing the halfway mark of 2020 and I am sure you agree it has had its challenges with the impact of COVID-19 on our global community.

From the CAP’s perspective most of our meetings are done by teleconference and while some face to face meetings have been cancelled, clinical trials remain vitally important. We have seen first hand just how hard the Study Chairs together with the Trial Management Committees have worked to ensure that the patients continue to receive vital treatment while reducing their exposure to infection of this virus. It is a very anxious time for patients, carers and their families who already have a cancer diagnosis to deal with. But they are certainly in good hands with the health professionals looking after the community and we thank them for their extra hard work during this time.

The CAP had its first teleconference for 2020 at the end of March and would normally be preparing for our face to face meeting at the full ASM which is now postponed to July 2021. In the meantime we will still be able to provide our input and advise from a community perspective as the engine room at ANZUP for developing and running clinical trials continues albeit just a bit differently.

Over the past few months, members of the CAP have been active on some interesting projects. Ray Allen (Deputy Chair) was invited to attend a Survivorship Essentials Expert Panel, with the Prostate Cancer Foundation of Australia. The project, conducted in an iterative Delphi format and comprising a series of online and face to face meetings, was aimed at identifying and prioritising the needs of prostate cancer survivors, with the added overlay of practical implementation.

The project created a focused input from the panel which included, oncologists, surgeons, recognised experts in quality of life care, nursing and survivor support. The results are still to be published but Ray believes that the output will be of great benefit to survivors.

Ray also attended a protocol development meeting to discuss Shahneen Sandhu’s concept: Lutetium-PSMA with ipilimumab and nivolumab in metastatic hormone naïve prostate Cancer (mHNPC). The trial aims to evaluate the safety and efficacy of combining a number of immunotherapy related cancer treatments in hormone naïve metastatic prostate cancer patients. The result of this study could potentially be practice changing. This meeting reminded Ray why ANZUP’s work is so important. The meeting was attended by a number of ANZUP’s senior clinical researchers who willingly provided their time and considerable expertise to review and help improve the study design. Ray commented that it was a privilege to be part of such a high energy working group and the CAP look forward to further involvement with this promising concept during the course of the year.

Matt Leonard was appointed as an Associate Investigator for the PERMEATE testicular cancer MRFF application. Thanks to Ben Tran, the principal investigator, who provided great feedback regarding Matt’s valuable contribution. Well done Matt.

Let’s hope the grant outcome is just as positive.

Hopefully by the time we write our next report, life will have settled somewhat but we all remain positive and accept change and we will continue to spend a bit more time on teleconferencing.

BELINDA JAGO & RAY ALLEN
Chair and Deputy Chair, CAP
Spotlight on SAC member, Pamela Russell (BSc, MSc, PhD, Dip Ed, AM FAHMS)

From her instrumental part in the establishment of ANZUP Cancer Trials Group, to a key member of the Scientific Advisory Committee (SAC), Pamela Russell is now stepping down from her role with the group. We are extremely grateful for everything she has contributed to ANZUP as well as to prostate cancer scientific research and autoimmune diseases. Pamela has accomplished an incredible amount over the course of her career and done so much for ANZUP and so many people. Read on for more about her remarkable career and time with ANZUP.

My scientific career began at Melbourne University when I studied for a Bachelor of Science, majoring in biochemistry and microbiology. I was then extremely fortunate to undertake an MSc under the supervision of Sir Macfarlane Burnet, a Nobel Prize winner. Following this, I completed a PhD with Sir Gustav JV Nossal on mouse models of autoimmunity. My great interest in “translational” research began at this time. I could see the possibility for research to translate to clinical treatments. My research enabled me to be the first to use cyclophosphamide as a treatment for some patients with Systemic Lupus Erythematosus. This treatment is still used for some patients 50 years later.

My career then led me to lecturing at both the Australian National University and the Canberra University and research at the Kolling Institute of Medical Science. Working with the oncologist Dr Derek Raghavan and the iconic urological surgeon, Dr Bruce Pearson, my research then moved to genitourinary oncology at the University of Sydney. Together we xenografted small fragments of bladder or prostate tumours from patients into nude mice to establish cancer xenograft lines that could be passaged from mouse to mouse in vivo. In addition, we established three new bladder cancer cell lines that could be passaged in vitro. In vivo studies using the bladder xenografts lines showed that a new drug, isopropyl cisplatin, was effective against bladder cancer and this has been translated to the clinic.

Around this time, I realised funding from NH&MRC was much higher for breast cancer than prostate cancer. I approached Roger Climpson, a television star, who suffered from prostate cancer, to see if he might help. Together with his Rotarian colleagues, we set up the Prostate Cancer Research Foundation, which subsequently joined with Prostate Cancer Support Groups to form the Prostate Cancer Foundation of Australia. I was an inaugural director.

With our immunology colleagues, led by Prof Tony Basten, from the University of Sydney, we made monoclonal antibodies against one of our bladder cancer lines that could be used to detect bladder cancer cells in urine specimens. One of the antibodies binds to glypican-1, expressed on prostate cancers, and some other solid tumours. Our preclinical studies showed that a derivative of this antibody had potential both for imaging and treatment of tumours when appropriately radiolabelled. At this stage in my career I continued these studies as Director, Oncology Research Centre at Prince of Wales Hospital in Sydney. And I have worked for the last 10 years with colleagues (Judith Clements and Colleen Nelson) on prostate cancer at the Australian Prostate Cancer Research Centre at the Queensland University of Technology, located in the Translational Research Institute, Queensland.

Whilst in Queensland, I was invited to be a member of the Movember International Committee. Their mandate was to bring together and competitively fund research groups to form international consortia who would share their experience and where possible, patient samples.

Research is a critical and necessary step in the development of new treatments, in ironing out difficulties experienced with current procedures and in moving forwards into new areas of endeavour to help treatment of patients with cancer.
to address difficult areas of prostate cancer research. As a member of this international committee, I was also a member of the Research Advisory Committee of Movember’s Global Action Plan One. Movember are now funding some clinical trials, including ANZUP’s TIGER trial for the treatment of germ cell tumours. Prior to the days of multidisciplinary team clinics to discuss patient treatments I realised there was a gap in knowledge of what differently skilled groups, such as oncologists, radiation oncologists, surgeons, scientists, pathologists and others were attempting to achieve. My colleagues from different disciplines and myself, set up the Genitourinary Oncology Group (GUOG) in an attempt to overcome this problem. The group was initially set up in NSW and eventually throughout Australia and New Zealand. This group enabled people to interact in their research and clinical studies and develop friendships with people in different disciplines. We also ran a series of expert led education programmes and three international conferences but did not fully attain our goal of increased involvement in clinical trials. Then around this time development of ANZUP began. I was delighted to join the discussions which led to the formation of the group and I joined the initial board.

ANZUP was able to fulfil the need for collaboration on clinical trials along with a multidisciplinary focus. My involvement with ANZUP has demonstrated their special role in listening to the patient voice as well as their commitment to running clinical trials for urogenital cancers, some led in Australia or New Zealand and others by international colleagues.

As I step away from ANZUP I am happy to say I have had the pleasure of being a part of their continued development and growing reputation. Their annual scientific meetings provide a paradigm for other groups. They are increasingly well attended and allow vigorous discussion and other interactions between invited international experts, Australian and New Zealand specialist groups and younger medical personnel, nurses, researchers, clinical trials specialists and psychologists. In addition, the ASM provides an open platform for questions and discussion with patients and their loved ones. Research is a critical and necessary step in the development of new treatments, in ironing out difficulties experienced with current procedures and in moving forwards into new areas of endeavour to help treatment of patients with cancer. There is still so much more that can be done in urogenital oncology clinical trials. My belief is that combination therapies will become a more prominent feature of new clinical trials. Immunotherapy together with current therapies is already being proposed for bladder, renal and other cancers. Understanding the role of the microbiome in the response to therapy will become an increasing area of research given the role of the gut in stimulating immune responses and how this can be affected by “bad” bacteria. Combined preclinical and clinical studies of patients with melanoma have shown that the microbiome can affect responses to immunotherapy or combined therapy for treating this cancer. In addition, given the enormous costs involved in the development of new drugs, I believe there will be an increased energy in studies for repurposing existing drugs. All of this indicates ANZUP will continue down its very successful path.

I would like to thank ANZUP for the friendships made, the strategies developed whilst on the SAC, the urogenital clinical trials that have progressed, the highly successful fundraising undertaken and ultimately for raising awareness and helping in the treatment of urogenital cancers. ANZUP has, and will continue to be at the forefront of many clinical trials for bladder, germ cell, renal, prostate and kidney cancers and I wish them every success for the future.

Spotlight on SAC member, Pamela Russell (BSc, MSc, PhD, Dip Ed), AM FAHMS

There is still so much more that can be done in urogenital oncology clinical trials. My belief is that combination therapies will become a more prominent feature of new clinical trials. Immunotherapy together with current therapies is already being proposed for bladder, renal and other cancers.
Dr Cristiane Decat Bergerot is a psychologist from Brazil with expertise in Health Psychology and Behavioral Science. She has been working with cancer patients for almost 15 years as a clinician and as a researcher. Over this period, Cristiane has had the opportunity to implement a biopsychosocial screening program at her parent institution.

Cristiane has also published several datasets that focus on biopsychosocial distress and sources of distress in patients with advanced renal cell carcinoma, whilst being a pioneer in the emerging field of psychogenomics, correlating genomic findings with psychological status.

She has recently completed an extended postdoctoral fellowship at City of Hope in the Genitourinary Department. Her central clinical interests lie in; the psychosocial aspects of cancer, evidence-based practices, patient reported outcomes, shared decision making, gender and age-based differences in the cancer experience among different patient populations, including underserved groups.

The focus of Cristiane’s research is medical factors and their psychological correlates, internet and mobile based interventions. From the perspective of clinical trials research, Cristiane’s main interest lies in psychosocial intervention and cognitive impairments associated with hormone-based therapy.

As a member of our international faculty for the ANZUP 2021 ASM, Cristiane looks forward to the wonderful opportunity to share thoughts and ideas on the landscape of genitourinary treatment, psychosocial aspects of cancer and associations between medical factors and psychological issues.

We look forward to hearing from Cristiane at the ANZUP 2021 ASM, where she endeavours to cover patient reported outcomes in urologic cancer, shared decision making and patient’s perceptions of cures.
Making ANZUP tick: Meet our Volunteers

For the past decade, ANZUP has had the privilege of working with two committed volunteers – Jo Stubbs and Lesley Tinkler – whose ongoing dedication to supporting ANZUP has been vital. We took the opportunity to sit down and chat with Jo and Lesley, to find out what inspired them to volunteer, what they have learnt from their time at ANZUP and what their favourite part has been on their volunteering journey.

You have both been such dedicated and committed ANZUP supporters for many years now. How long have you been volunteering with ANZUP?

Lesley: I’ve been here 9 years, so I’ve been here since ANZUP was small. When you stop and look at what’s been achieved… the growth has been really rapid.

Jo: I’ve been here for 8 years. When we started it was just Margaret (ANZUP CEO), one part time staff member and Lesley… so the ANZUP empire has grown somewhat (laughs).

How did you learn about ANZUP, and what inspired you to start volunteering?

Lesley: I was friends of a friend of Margaret’s. I had a little bit of time and I didn’t want to fill it up with nothingness. I started coming in one day a week and it’s continued on for 9 years now. It was daunting to me because I hadn’t worked for a while, but it has all worked out really well.

Jo: I met Margaret back in the late 80’s. About 9 years ago, she mentioned to me that she had started this new job, and she suggested that I come in and give Lesley a hand one day a week. Back then, we were so busy because we printed everything, including this consumer magazine, ourselves.

What’s your favourite part about volunteering at ANZUP?

Jo: We really have some permanence here. Week after week, we have established a routine that works. We know that what we are doing has meaning, and our role makes a difference.

Lesley: I’d say the people, and the satisfaction of knowing we’ve reached a stage where we can make small decisions and know we will be backed in that. Supporting Marg is at the foundation of our role at ANZUP, and it has been a pleasure to do so.

What’s something you’ve learnt from your work at ANZUP?

Jo: I have learnt that there are an incredible amount of people out there who are moving heaven and earth to find a cure for cancer. People who are so passionate about that being their job. It really blows me away. You attend something like the ASM and you think, there’s people really working on this, really trying to make a difference and it’s incredible to see.

What would you say to someone who’s considering volunteering?

Lesley: I think volunteering when you’re retired is essential. It is so enjoyable to spend time with younger people and learn new skills.

Jo: We’ve really learnt so much about what life today is like. Social media, and how to use it effectively, I’d never understood any of that. Volunteering can help you keep up with technology. Also - you’ll never be thanked so much in your life. The gratitude is astounding.
Fundraising Heroes – Bev & John Purvey

Special thank you to Bev and John Purvey for choosing ANZUP as their charity of choice for their 70th Birthday Party celebration. In lieu of gifts, it was suggested that guests consider a donation to bladder cancer research conducted by ANZUP. What a collective gift! Over $10,500 was kindly donated. Bev was diagnosed with bladder cancer in 2018 and is now recovering from her latest treatment. It is her mission to share her experience and inform people about the signs and symptoms of this rare cancer. Bev is happy to tell her story in the future to help raise awareness and even more funds for ANZUP.

The party, held at The Pullman on the Park, Melbourne was a wonderful celebration of their birthday milestone, with over 100 guests including her specialist and ANZUP Board Director Prof Shomik Sengupta and CEO Margaret McJannett. Entertainment for the night was the fabulous Kylie Minogue show. Fun was had by all while supporting a great cause.

Upcoming Events 2020

- **29-31**
  - 2020 ASCO ANNUAL MEETING
  - VIRTUAL

- **18-22**
  - ESMO CONGRESS
  - MADRID

- **11-13**
  - COSA ASM

- **Date TBC soon!**
  - ANZUP MINI-ASM
  - MELBOURNE
ANNUAL SCIENTIFIC MEETING

ADELAIDE CONVENTION CENTRE
18-20 JULY 2021