Clinicians working in cancer care are exposed to rapid changes in practice. One could argue that we are ‘change junkies’, easily seduced by new treatment philosophies. We embraced the explosion of targeted therapies, with rationally designed drugs blocking key pathways, leading to growth inhibition and clinical benefits across multiple cancer types, including renal and prostate cancers. More recently, however, we have been inspired by the promise of immunotherapy and by the sequencing of individual patient tissues to determine treatment. Does this mean, then, that targeted therapy development is behind us?

Prostate cancer has had an enduring targeted therapy in androgen inhibition, which has been revitalised with the development of abiraterone acetate and enzalutamide. These drugs effectively block signalling of the androgen receptor, even after the failure of systemic castration, delaying cancer symptoms and improving survival. However, targeted therapy successes in prostate cancer have been accompanied by many notable failures, despite pre-clinical data supporting a mechanistic role for the target and even in the face of promising early trials. Cabozantinib, the tyrosine kinase inhibitor that provided spectacular bone scan and clinical responses in Phase I development, recently failed to improve survival in a Phase III trial. Likewise, targeted therapies tested in combination with docetaxel chemotherapy in large and expensive trials have all failed to impact survival endpoints.

So, has the age of targeted therapy for urological cancers passed? Hopefully not – but cancer biology is complicated by multiple redundant pathways and feedback loops that are not well reflected by pre-clinical models. Smarter trial design is required, embracing translational technologies to interrogate the biology underlying clinical responses. Bravery is now required in seeking adaptive trial designs and in overcoming traditional boundaries of pharmaceutical companies, treatment modalities and even cancer types to develop the next generation of affordable, highly effective targeted treatments.

CARMEL PEZARO
Medical Oncologist and Senior Lecturer; Eastern Health Clinical School; Monash University.
ANZUP ANNUAL SCIENTIFIC MEETING
Redefining Personalised Medicine

Brian I. Rini, MD, FACP. Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University in Cleveland, Ohio. Brian’s primary research has been in renal cell carcinoma (RCC) and prostate cancer, with special focus on antiangiogenic therapy and immunotherapy.

Bertrand Tombal, MD, PhD. Professor Bertrand Tombal is Chairman of the Division of Urology and Professor of Urology at the Université catholique de Louvain (UCL), Cliniques universitaires Saint-Luc, Brussels, Belgium. He is the current chairman of the Genitourinary group of European Organization for Research and Treatment in Cancer, the leading European academic research organization in the field of cancer.

Chris Sweeney, MBBS. Associate Professor, Department of Medicine, Harvard Medical School and Dana-Farber Cancer Institute. Chris is a clinical oncologist and sits on the Scientific Advisory Committee of ANZUP Cancer Trials Group. His primary research interest is drug discovery and development. His academic focus is management of genitourinary malignancies, with a focus on prostate and testicular cancer.

Theodore DeWeese MD. Dr. DeWeese is Professor and Chair of the Department of Radiation Oncology and Molecular Radiation Sciences at Johns Hopkins University. He is also Professor of Urology and Oncology at Johns Hopkins and has a broad experience on which to draw regarding basic and translational cancer research.

The 2015 ANZUP annual scientific meeting, focusing on “re-defining personalised medicine”, is running from the 12 - 14 July at the Sofitel in Sydney. Confirmed international guests include Brian Rini, Bertrand Tombal, Chris Sweeney and Theodore DeWeese. They will be joined by a diverse group of local faculty to deliver sessions focusing on a variety of genito-urinary malignancies.

In addition to state-of-the-art presentations, we will again aim to highlight clinical trials, with reports on current ANZUP trials, and opportunities to develop new trial concepts. Abstract submissions and proposals for clinical trial concepts will open in the New Year. The MDT Masterclass will continue as an opportunity to review challenging cases with a multidisciplinary panel of experts and the audience.

VENU CHALASANI
ASM Convenor 2015
For more information visit www.anzup.org.au

2014 has been another extraordinary year for ANZUP. I seem to say something similar to that every year, but the momentum of the organisation, the quality of its work, and the importance of the outcomes continue to progress in ever-increasing leaps and amaze even those of us closest to it. Here are some of our highlights from 2014.

- Initiation for ENZAMET and ENZARAD. These two large international prostate cancer trials are the biggest and most ambitious we have yet undertaken. We were able to meet our tight deadline of opening both studies before the end of March 2014. Most Australian sites are now open and accruing well and we will soon be opening international sites. There has been considerable international interest in both trials and we hope that the studies will provide information that will change clinical practice. Our first international sites (NZ) have just been activated for ENZARAD – for both Christchurch and Auckland Hospitals.

- Opening of phase 3 accelerated BEP testicular cancer trial and BCG/mitomycin non-muscle-invasive bladder cancer trial. Both of these trials came through the ANZUP systems and successfully obtained competitive grant funding. Thanks and congratulations to the lead investigators Peter Grimison and Dickon Hayne, as well as to the much larger cast and crew at ANZUP and the NHMRC Clinical Trials Centre who helped get us to this point.

- Other trials are about to open (eg BL12 second line urothelial cancer led by Ben Tran) or are successfully completing accrual (eg gay and bisexual men led by Jane Ussher). These trials take us into areas where there are important clinical needs and ANZUP is uniquely placed to answer these questions. Both these trials also represent new or expanding collaborative connections.

Continued over...
• Several grant applications were submitted for other projects and these results have now been announced. ANZUP was successful with the “Pain Free TRUS B” prostate cancer trial application, with funding support to come from Cancer Australia and the Prostate Cancer Foundation of Australia. Two other applications were not funded but did score highly at the initial stringent hurdle of NHMRC Grant Review Panel assessment and were ranked in the fundable range. We have done very well by national standards and I congratulate everyone involved.

• Another highly successful Annual Scientific Meeting and Masterclass. I have written about this in previous newsletters. Planning is well underway now for the 2015 meeting.

• Continued growth in membership and increasing engagement in ANZUP activities by members. It is great to see people contributing in various ways and stepping into leadership roles.

• Amazing fundraising efforts and outcomes such as the Pedalthon in September. Not only did it lead to an amazing financial result, but perhaps more importantly it increased awareness and the profile of these cancers and underscored the importance of clinical trials to improve outcomes. That is precisely what we are about. I particularly want to acknowledge the tireless efforts of Simon Clarke in bringing this event to reality, as well as our sponsors particularly Gresham Partners, International Towers Sydney, Herbert Smith Freehills and Thomson Geer Lawyers. We must not forget those who contributed either financially, or through physical pain, or both – what amazing efforts! Save the Date! September 1, Pedalthon 2015.

We are astonished and gratified by all of this but we know that there is still so much more to do. ANZUP has now positioned itself as the key group involved in multidisciplinary genitourinary research across Australia and New Zealand and is increasingly being recognised internationally for its work. Our various subcommittees provide continuous input to the Scientific Advisory Committee to help us set our strategic direction. Our Consumer Advisory Panel keeps us aligned with the community’s needs and helps us as we communicate back to the community about the importance of this research and its outcomes. All of these people contribute selflessly and without fanfare but are indispensable for our success.

There are opportunities for all our members to participate. Think about how you might want to contribute, by driving the scientific agenda through the subcommittees, or driving the trials at your site, or by continuing to raise awareness of ANZUP, the cancers we are here to overcome, and the importance of supporting clinical research. We have tools to assist you such as the ANZUP ClinTrials Refer app, available for free through the iTunes store or for Android devices. This intuitive app will give you all the information you need about ANZUP trials including the clinical sites, trial eligibility criteria, and other links. Perhaps you could encourage your colleagues and your patients to have a look at it.

ANZUP plans to continue to grow and evolve. Eventually we want to be in a position where we can initiate and even complete clinical trials without the need for grant funding. This will involve securing substantial additional recurrent funding and our fundraising programs are an important part of that. Some of you might be in a position to promote ANZUP to industry or philanthropic sources of funding. We would be glad to provide any information you might need to facilitate this – please contact our office.

I cannot close without acknowledging the people who work so hard to ensure ANZUP’s success. Thanks to the Board, who are always so supportive and responsive; the members of the Scientific Advisory Committee and subcommittees; the Consumer Advisory Panel; our office team of Marg McJannett, Liz Thorp, Yi Feng and Jenni Beattie; our volunteers Lesley Tinkler and Jo Stubbs; our collaborators at NHMRC Clinical Trials Centre; our hardworking investigators and site study coordinators; our supporters, stakeholders and funders; and of course our patients, who so selflessly volunteer their time and tissues to help make a difference. It is humbling to see, and it’s a privilege to be part of it.

Please enjoy this edition of UPdate.

IAN DAVIS
Chair, ANZUP
What a year we have had! As the festive season is upon us I think it is worth taking a moment to reflect on the some of the highlights over the past 12 months. It certainly was a year of ‘firsts’.

- Our inaugural Community Newsletter ‘A little below the belt’ was launched in April, with our second edition just published. It is our intention that this publication will provide our consumer community accessible and accurate information on the work ANZUP does. Please consider placing it in your waiting rooms and sharing with your patients. You can access it via the ANZUP website, or contact the ANZUP secretariat.

- The inaugural Tolmar/ ANZUP Uro- Oncology Clinical Research Fellowship (CRF) was awarded to Dr Ben Tran in September. The CRF is intended to support early/mid career clinician-researchers of any health care discipline. We plan to call for applications for the 2015 CRF in March with the successful applicant announced at the ANZUP ASM. So make sure you look out for further information. We thank Tolmar Australia for supporting this excellent initiative.

- ClinTrial Refer ANZUP App was launched at this year’s ASM. The app provides a current list of ANZUP clinical trials conducted in cancer centres in Australia and New Zealand. It is designed for oncologists, general practitioners, research unit staff and patients. It has searchable clinical research trial details, hospital locations, inclusion and exclusion criteria, and lay summaries. We hope this will help all our members as well as the broader community to identify trials that might be suitable. To download the free app, visit: Apple iTunes: https://itunes.apple.com/au/app/clintrial-refer-anzup/id894317413?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.lps.anzup&hl=en

- We launched our first major fundraising event the ‘Below the Belt Pedalthon’ at Eastern Creek on 16 September 2014. Through Simon Clarke’s extraordinary determination and commitment, with great support from the ANZUP team of workers and volunteers the Pedalthon was by all measures a HUGE success. Not only did it raise significant funds to support ANZUP’s research activities but opened the door for us to better engage with the Corporate sector. Our sincere thanks to Simon, and his wonderful family and friends for their support and generosity. To Peter Grimison a big thank you for suggesting Simon speak to us. The funds raised from the Pedalthon have already made a difference supporting our recent first face to face Concept Development Workshops to progress our clinical trials research (you can read more about this on page 16).

- Best of GU Oncology symposium held at Pier One Sydney on Wednesday November 5 was also another first! We had a fantastic turnout for a weeknight with more than 65 delegates in attendance. Our thanks to Henry Woo who did a superb job developing the program and facilitating the night. Thanks also go to our speakers Ian Davis, James Kench, Scott Williams and Nick Brook who provided the audience with the most relevant, cutting-edge research and treatment in prostate and urogenital cancer. This was another successful collaboration between ANZUP and USANZ. We gratefully acknowledge the generous support of our Corporate Supporters Amgen, Ipsen, Sanofi and Janssen which enabled us to convene our evening symposium.

- Our 5th ASM was a resounding success. Officially opened by Victorian Parliamentary Secretary for Health Ms Georgie Crozier MLC, delegates were treated to a high-quality scientific program over the three days. We had even more delegates demonstrating the continuing growth of ANZUP and our international faculty were extremely generous with their expertise and engagement with members throughout the meeting. These delegates were supported by a superb line-up of local speakers and a record number of poster presentations.

A big thank you to this year’s convenor David Pook, along with his committee Carmel Pezaro, Belinda

SAFE & HAPPY HOLIDAYS
Jago, Shankar Siva, Andrew Weickhardt, Emma Beardsley, Kath Schubach and Ben Tran for all their efforts. Thanks also to Ian Davis, Henry Woo and Shomik Sengupta who provided additional support and guidance to the committee. Thank you also to Kate Murphy and Jayme Goulter at YRD who organised the logistics of the meeting.

This year, we decided to change the name of the Trainee Day to be the MDT Masterclass, reflecting ANZUP’s focus on the multidisciplinary management of urological cancers. The feedback was extremely positive not only from our medical, surgical and radiation oncology colleagues but also from our Allied Health Professional members who found the day valuable and relevant. Thank you to our Masterclass convenor Andrew Weickhardt, and our expert panellists who generously donated their time, not to mention their Sunday, to participate and contribute to the success of the day. Thank you to our MDT Masterclass sponsor Janssen for their support.

Our Community Engagement Forum is our opportunity to provide the general public with information about ANZUP, the importance of clinical trials and the impact a diagnosis of a urogenital cancer can have on a person and their family. The experienced team of ANZUP members who joined us on the day engaged and encouraged audience participation. Connecting with the community can be quite a challenge and this year, largely due to the efforts of Liz Thorp, we had more than 65 community members attend – a significant increase on last year. Please consider promoting these events to your patients and their families.

None of this would have been possible without the generous support of our 2014 ASM sponsors and I would like to express my gratitude to Janssen, PCFA, Tolmar Australia, Sanofi, Astellas, Pfizer, GSK, Ipsen, Amgen, AstraZeneca, Bayer, Ferring and the State Government of Victoria. We are also grateful to Bayer for supporting the ANZUP Bayer Travel Fellowships and Astellas for the Best of the Best Oral and Poster Awards.

We are also extremely grateful to our Consumer Advisory Panel for their continued support and collaboration during 2014. Their involvement in many disease specific teleconferences and ASM planning is vital to ensure we continue to have a consumer voice at the table.

A big thank you to the well-oiled machine which is the back office of ANZUP. Thank you to Yi Feng, Liz Thorp and Jenni Beattie for all their efforts and support. To our fantastic volunteers, the lovely Lesley Tinker and Jo Stubbs, thank you. I think the whole 6th floor looks forward to your weekly visits. Thank you also to Trevor Back, John Stubbs, Burcu Vachan and Nicole Wong who volunteered for the Pedalthon. We couldn’t have done it without your help.

We are truly grateful to all the Chairs for their significant and regular contributions they make, this is on top of what is already a full and hectic timetable.

A heartfelt thank you to Ian Davis, ANZUP’s enthusiastic and tireless Chair, who not only contributes to all ANZUP’s research activities but also gives feedback in record breaking time! To Deputy Chair, Guy Toner, Joe Esposito, Henry Woo, Glenn Ferguson, Liz Kenny, Martin Dowling and Linda Martin. Thank you for your support and expert guidance over the last 12 months to ensure ANZUP’s sustainability and continued growth.

Have a lovely festive season and a well-deserved break.

MARGARET MCJANNETT
Executive Officer

p.s. Don’t forget to SAVE THE DATE for the Annual Scientific Meeting 12-14 July 2015 in Sydney. Please encourage your friends and colleagues to come along. We look forward to seeing you there!

Twitter

Did you know ANZUP is tweeting? If you aren’t already following us you can find us at @ANZUPtrials. We hope all ANZUP members with twitter accounts will start following us.

Key dates, trials updates, news and good news stories are regularly being tweeted.
We are very grateful for the infrastructure support we receive from Cancer Australia however the funds are not sufficient to support ANZUP’s increasing research activities.

In 2012 we established our Corporate Supporter program and are delighted that this program has continued this year to grow and we welcome additional industry partners Astellas and Janssen. Through this program we have made significant inroads to supporting and facilitating better engagement with our members.

We welcome and acknowledge our corporate supporters and partners for 2014.

Run for ANZUP!

ANZUP is now a listed charity with the Sydney Morning Herald Half Marathon. So if you prefer a run to a ride or love them both, you can select ‘ANZUP Cancer Trials Group’ as the recipient of your fundraising efforts.

We would love to see ANZUP members, donors, friends and family challenge themselves and each other, to raise funds during the SMH Half Marathon on Sunday 17 May, around beautiful Sydney Harbour.


Thank you and have a great time. Don’t forget to tweet @ANZUPtrials or send us your photos!
The SAC had its annual face-to-face open meeting on Sunday 13 July 2014 at the Annual Scientific Meeting and met again on 26 November 2014 by teleconference. Activity since the July meeting has mainly been at the level of the subcommittees and especially in the context of the Concept Development Workshops. These workshops will result in new proposals to be matured and taken to the SAC for discussion and prioritisation. However, this is not the only mechanism for concepts to move through the system and several others are at various levels of development.

ANZUP takes pride in the broad multidisciplinary representation it has on the SAC and its ability to move swiftly and effectively when required. The work of bringing trial concepts through to maturity cannot be overstated: it takes enormous time and effort from many people. The SAC must also impartially assess each proposal in the light of ANZUP’s strategic direction, to ensure that those that move forward are the right ones and best able to generate meaningful outcomes and hence influence practice and policy. The SAC is ably assisted in this by the Consumer Advisory Panel, and also by the Board. All ANZUP members can influence these processes through their participation in the subcommittees, so if you have ideas, please ensure you bring them to us. One of ANZUP’s goals is to nurture the next generation of clinician-scientists who will take up these roles and responsibilities in the future. There are many supports available to this end so make sure you take advantage of them and introduce your colleagues and trainees to them.

Thanks to everyone involved for your efforts to help ANZUP reach its vision of improved outcomes for our patients and their families.

IAN DAVIS
Chair, Scientific Advisory Committee

**MARKETING UPDATE**

**New ClinTrial Refer ANZUP App**

The ClinTrial Refer ANZUP app provides a current list of clinical research trials conducted in cancer centres in Australia and New Zealand.

Designed for oncologists, general practitioners, research unit staff and patients, ClinTrial Refer ANZUP has searchable clinical research trial details, hospital locations and contacts, and inclusion and exclusion criteria.

To download the free app, please visit:
- **Apple iTunes**: https://itunes.apple.com/au/app/clintrial-refer-anzup/id894317413
Worldwide BCG shortage

Bladder cancer care in Australia has been seriously compromised by a world shortage of BCG. This affects all patients with intermediate and high risk non-muscle-invasive bladder cancer (NMIBC) in whom BCG constitutes part of their treatment. Enrolment to the BCG/MMC trial has had to be suspended and remaining stocks conserved for those patients at most need of BCG or already enrolled in the trial. USANZ has issued guidelines on the management of NMIBC in the absence of BCG which can be accessed via:


Merck, who produce the currently most widely available brand of BCG Oncotide (Tice strain), hope that supply may be re-instated to Australia in early 2015 though this has yet to be confirmed.

Both the ‘chemotherapy in advanced urothelial cancer in patients with renal impairment’ application and the ‘OPTIMUM’ application scored sufficiently in the NHMRC assessment however unfortunately were not successful.

New Concepts Meeting

Several new concepts were put up to the sub-committee and we had the opportunity to discuss these at our recent face to face workshop in Sydney on Friday 21st November. Small working groups will continue to progress these over the coming months.

DICKON HAYNE
Chair, Bladder Cancer Subcommittee

ANZUP Membership benefits include:

• Access to a multidisciplinary network for Urogenital and Prostate cancer researchers, including clinicians, nurses, psychologists, scientists, allied health and consumer representatives

• Opportunity to contribute to the scientific and strategic development of ANZUP through its SAC and subcommittees

• Support for the development of investigator-initiated studies

• Mentoring and support of young investigators across all our research activities

• ANZUP newsletter UPdate and regular sector news updates

• Discounted registration at ANZUP’s annual scientific meeting

• Access to educational resources, workshops and seminars

• Access to grant opportunities

• Voting rights at ANZUP annual general meeting and other general meetings

• Other benefits that will be extended from time to time for members only

Please join the group and take advantage of the many opportunities for training and mentorship. Maybe you’ll be a future leader of genitourinary cancer research, and maybe you’ll make the current leaders less crusty.

There is currently no membership fee and membership does not need to be renewed annually at this stage. Find out more http://www.anzup.org.au/members.aspx.
The germ cell subcommittee continues to be very active in 2014.

Phase III RCT of accelerated BEP (plus translational sub study) - Now open at 23 sites and recruiting!

This randomised trial of chemotherapy with accelerated BEP versus standard BEP for patients with intermediate or poor-risk advanced germ cell tumours is supported by Cancer Council Australia and Cancer Australia. 23 of 29 ANZ sites have been activated, and three patients have been recruited from Concord Hospital (PI Martin Stockler), Austin Hospital (PI Andrew Weickhardt), and Prince of Wales Hospital (PI Elizabeth Hovey). Please see protocol summary on next page. Our trial coordinator Annie Yeung, Associate Oncology Program Manager Nicole Wong, and ANZUP research fellows Felicia Roncolato and Anne Long continue to work behind the scenes on this important study. If you have any questions in relation to this study, then please use the p3bep@ctc.usyd.edu.au email address.

e-shed survivorship interventional study

This study is developing an internet-based intervention to address psychosocial distress for survivors of testicular cancer, and is being conducted by the Psycho-Oncology Co-operative Research Group (PoCoG) in collaboration with ANZUP and Swinburne University of Technology. 21 participants have been involved in the pilot phase of the study recruited from 5 pilot sites in NSW and Victoria, led by Research Coordinator Dr Louise Heiniger from PoCoG, with evaluation ongoing. Dr Ben Smith from PoCoG is leading the development of a subsequent phase 2 study.

Updates from studies in follow-up

1. “Chemotherapy and Cognition”:
Statistical analyses by COGSTATE continue for this study of 150 patients led by Prof Ian Olver, which has prospectively monitored cognitive function in patients managed with and without chemotherapy for testicular cancer.

2. “Phase II study of accelerated BEP for advanced germ cell tumours”:
Follow-up is ongoing for this study, with an updated 5-year analysis planned for the end of 2015.

Movember

ANZUP was selected to participate in the next phase of the Movember GAP5 Translational Research Project, which is a translational project that aims to identifying the biological drivers of relapse in this cohort of men through collection and analysis of tissue, blood or urine samples in men who relapse after primary curative therapy. I attended a steering committee meeting in Los Angeles Tuesday September 30 – Wednesday October 1, 2014. A steering committee consensus document will be submitted to the GAP5 research advisory committee, and it is hoped that ANZUP and its Australian collaborators will have the opportunity to participate in this research.

Current concepts in development

Concepts in development include a study for stage 1 testicular cancer addressing promotion and patterns of surveillance, and unmet needs; and a national germ cell registry for which pilot funding has been awarded by Cancer Australia to three cancer centres in Sydney, Melbourne, and Adelaide. ANZUP continues its dialogue with Movember regarding participation in the TIGER study, which is an international randomised trial of high-dose chemotherapy with TI-CE versus conventional-dose chemotherapy with TIP for refractory and relapsed germ cell tumours that will be sponsored by EORTC and funded by Movember in Europe.

Call for new members

The Germ Cell Sub-committee always welcome new members including trainees who will contribute to research activity. Please encourage your interested colleagues and trainees to join the sub-committee. We are a multi-disciplinary group, and we encourage participation of members not only from medical oncology, but also from surgery, radiation oncology, nursing, psycho-oncology, and basic science. Again I thank the efforts of investigators, staff from ANZUP and the CTC, and patients for these achievements.

PETER GRIMISON
Chair, Germ Cell subcommittee
PROTOCOL SUMMARY

A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for participants with intermediate and poor-risk advanced germ cell tumours

Trial Aim:
To determine if accelerated BEP is superior to standard BEP as first-line chemotherapy for intermediate and poor-risk advanced GCTs.

Primary objective - To compare PFS amongst participants randomised to standard BEP or accelerated BEP.

Secondary objectives - To compare Overall survival, Response rates, Adverse events, Health-related quality of life, Preferences, and Delivered dose-intensity of chemotherapy

Translational objectives - To determine associations between biomarkers and their correlations with clinical outcomes

Study Population:
Male participants aged between 16 years and 45 years with advanced germ cell tumours (NSGCT or seminoma) of intermediate or poor prognostic category by modified IGCCCG criteria with adequate bone marrow, hepatic and renal function.

Trial Design:
Open-label, randomised, 2-arm, multicentre, phase 3 clinical trial.

Recruitment Target:
Part I of the trial aims to recruit 90 patients from about 25 sites in Australia and New Zealand, and an additional 60 patients from international sites in the United Kingdom and USA. Part 2 of the trial would recruit an additional 350 patients and is dependent on involvement of international trial groups.

Study treatment:
Participants will be randomised to either “standard BEP” or “accelerated BEP” arm as follows:

Standard BEP arm
Participants will receive 4 cycles of Standard BEP as follows:

- Bleomycin: 30,000 international units IV weekly (eg. days 1, 8 and 15 or days 2, 9 and 16)
- Etoposide: 100 mg/m² IV on days 1, 2, 3, 4, 5
- Cisplatin: 20 mg/m² IV on days 1, 2, 3, 4, 5
- Pegylated G-CSF 6mg SCI on day 6

Treatment is repeated every 3 weeks (21 days). The planned total duration of treatment is 12 weeks.

Accelerated BEP Arm
Participants will receive 4 cycles of Accelerated BEP as follows:

- Bleomycin: 30,000 international units IV weekly (eg. days 1 and 8 or days 2 and 9)
- Etoposide: 100 mg/m² IV on days 1, 2, 3, 4, 5
- Cisplatin: 20 mg/m² IV on days 1, 2, 3, 4, 5
- Pegylated G-CSF 6mg SCI on day 6

Treatment is repeated every 2 weeks (14 days). Following the above regimen, an additional 4 weekly doses of bleomycin 30,000 international units will be given. The planned total duration of treatment is 12 weeks.
The past quarter in the Prostate Cancer Subcommittee has been one of consolidation and planning. Our primary focus has remained on the enzalutamide studies:

- **ENZAMET**: Randomised phase III trial of testosterone suppression with or without enzalutamide as first line therapy for metastatic prostate cancer.

- **ENZARAD**: Randomised phase III trial of radiation plus androgen deprivation therapy with or without enzalutamide as first line therapy for high risk, clinically localised prostate cancer.

ENZAMET continues to do well having now recruited 72 participants. A major amendment has now been approved by central ethics that incorporates data from the CHAARTED study, with stratification for the planned early use of docetaxel chemotherapy. The decision regarding early use of docetaxel must be made prior to randomisation, and men who have received up to 2 cycles of docetaxel already can also be enrolled. The study also stratifies for volume of disease in a manner analogous to CHAARTED, and will potentially allow subset analyses paralleling CHAARTED with and without enzalutamide.

ENZARAD has now up to 27 cases, with still only 14 sites open. I encourage all those who are planning to participate and haven’t as yet submitted the radiation benchmarking exercises to do so as soon as possible. This can all be done ahead of ethics submission. We are hopeful that sites in the UK and Ireland will open soon. Discussions are ongoing regarding bringing USA / Canadian and European centres on board also.

I remind all members that materials from the investigator meeting are available on the secure section of the ANZUP website. **Webcast**: ANZUP members who are participating in the ENZAMET and ENZARAD trials are registered to access the webcast. Please visit http://www.webcasts.com.au/ANZUP190314/, click on the session link and enter your email address on the following page. When viewing the webcast you can skip through the presentations by clicking on the ‘Chapter Selection’ button located on the bottom right corner of the video player page. **PowerPoint Presentations**: To access the PowerPoint Presentations please visit http://www.anzup.org.au/content.aspx?page=enzamet-enzarad-im and log in with your ANZUP username and password.

We continue to support our portfolio of cobadged clinical trials.

- The ProCare phase I/II randomised controlled trial of follow up of men with prostate cancer in primary care (PC4 led), is in follow-up.

- The RAVES study (TROG led), a phase III multi-centre randomised trial comparing adjuvant radiotherapy (within 4 months of surgery) with early salvage RT continues to accrue slowly. I urge ANZUP members to continue to keep identifying potential participants for this study wherever possible. Several substudies - germline DNA collected for a genetic epidemiology register, tissue banking of the primary specimen and a randomised decision aid study – are also open now.

- The Randomised Controlled Trial of a Mindfulness Intervention for Men with Advanced Prostate Cancer (“Living Well with Prostate Cancer”; CCQ/Griffith University led) is progressing well.

- Prostate Cancer and in Gay and Bisexual Men and Their Partners Study, led by UWS: Recruitment now includes a comparison group of heterosexual men. Initial enrolment in the study is via the website and will continue until the end of this year (www.uws.edu.au/PCAS).

We have been advised that the “Pain Free TRUS B” prostate cancer trial application was successful. There are numerous concepts being worked up within the group also at present, including several that were highlighted at the recent ASM concept development session. We also held our first concept development meeting in Sydney on November 5th. This was a very successful meeting, with two concepts discussed extensively, and several other possibilities broached. These are outlined in the prostate subcommittee teleconference minutes presently being sent to the more than 250 ANZUP members who have nominated an interest in prostate cancer.
The RCC subcommittee has continued to meet quarterly by teleconference. Our two currently active trials (SORCE and EVERSUN) are closed to accrual but we continue to follow patients. The EVERSUN trial manuscript has been submitted for publication. SORCE is still a long way from completion but interesting data continues to come from it, including further outcomes from the patient preferences PAS in SORCE sub study led by Prunella Blinman and Martin Stockler.

The committee has recently completed a survey of radiation therapy practice in the setting of renal cell carcinoma and this work is planned for publication. SORCE is still a long way from completion but interesting data continues to come from it, including further outcomes from the patient preferences PAS in SORCE sub study led by Prunella Blinman and Martin Stockler.

The committee has recently completed a survey of radiation therapy practice in the setting of renal cell carcinoma and this work is planned for publication. It also lays the groundwork to support future trial concept development in this field.

The Concept Development Workshop on 21 November 2014 included discussion of several trial concepts, reflecting our recognition of areas of clinical need and unanswerd clinical and biological questions. We expect that one or more of these will move rapidly into further development.

The Renal Cell Cancer subcommittee welcomes new members and is open to any thoughts or ideas its members might contribute.

IAN DAVIS
Chair, RCC subcommittee

The Prostate Cancer Sub-committee always welcomes new members including trainees who will contribute to research activity. Please encourage your interested colleagues and trainees to join the sub-committee.

SCOTT WILLIAMS
Chair, Prostate Cancer Subcommittee

The Prostate Cancer Sub-committee always welcomes new members including trainees who will contribute to research activity. Please encourage your interested colleagues and trainees to join the sub-committee.

ProstateApp Launched

Australian men are now able to access prostate cancer information at their own convenience with ProstateApp developed by the Prostate Cancer Foundation of Australia (PCFA)

ProstateApp is the first app to assist men and their families navigate the emotional, psychological and physical challenges that come with a prostate cancer diagnosis.

The app is based on the book “Facing the Tiger: A guide for men with prostate cancer and the people who love them” by Professor Suzanne Chambers and can be used independently or in conjunction with the book.

Developed by PCFA, the app features practical tools like activities on decision making, guides on self-care and links to organisations. It also includes supportive elements such as videos of people talking about their experiences, inspirational quotes and daily motivation during the prostate cancer journey. The activities and exercises are also underpinned by principles of cognitive behavioural therapy.

ProstateApp is now available through the App Store.


ProstateApp Launched

Australian men are now able to access prostate cancer information at their own convenience with ProstateApp developed by the Prostate Cancer Foundation of Australia (PCFA)

ProstateApp is the first app to assist men and their families navigate the emotional, psychological and physical challenges that come with a prostate cancer diagnosis.

The app is based on the book “Facing the Tiger: A guide for men with prostate cancer and the people who love them” by Professor Suzanne Chambers and can be used independently or in conjunction with the book.

Developed by PCFA, the app features practical tools like activities on decision making, guides on self-care and links to organisations. It also includes supportive elements such as videos of people talking about their experiences, inspirational quotes and daily motivation during the prostate cancer journey. The activities and exercises are also underpinned by principles of cognitive behavioural therapy.

ProstateApp is now available through the App Store.

Living Well with Prostate Cancer - active and recruiting!
The NHMRC-funded Living Well with Prostate Cancer is trialling the effectiveness of a mindfulness-based cognitive therapy group intervention over the telephone for men with advanced prostate cancer. Ten intervention groups have now been completed and the last groups will be conducted in early 2015. Men who participated in the groups have continued to provide positive feedback to the project team about the program.

The project now has a total of 171 men enrolled and recruitment will be closing for this project at the end of 2014. We still have another 19 men needed to reach our target of 190 participants so any referrals in this final month of recruitment would be greatly appreciated.

Cancer Council Queensland and Griffith University would like to thank all the ANZUP members involved with the project across our 40 recruiting sites for all of your hard work referring patients. If you would like any more information about the project, please contact the Project Manager, Rob McDowall, on (07) 3634 5314 or email robmcdowall@cancerqld.org.au.

Prostate Cancer in Gay and Bisexual Men and their Partners Study
The Prostate Cancer in Gay and Bisexual Men and their Partners Study aims to gain knowledge and understanding of how prostate cancer affects sexual wellbeing and quality of life in gay and bisexual men and their partners.

The study has successfully recruited 137 gay and bisexual men and 27 male partners to complete the study survey. In addition, 46 gay and bisexual men and 7 male partners have participated in an interview in order to gain a deeper understanding of their experiences. Additionally, 239 surveys and 19 interviews have been completed by heterosexual men. The purpose of this heterosexual comparison sample is to allow for greater insight into the specific needs and experiences of gay, bisexual, and heterosexual men to inform more targeted health care provision and ongoing support post cancer.

Cancer Australia Chair in Cancer Quality of Life and the Quality of Life Technical Service

The Quality of Life (QOL) Office is pleased to commence a third contract with Cancer Australia, as providers of the Quality of Life Technical Service to the Australian Cancer Co-operative Clinical Trials Groups (CCTGs) for the period of 1 July 2013 – 30 June 2016.

The QOL Office offers a range of services to members of ANZUP, including:

- a number of free web resources, including a checklist of items to include in the QOL sections of your trial protocol, information about common QOL measures and information about how to analyse QOL data;
- an advisory service - to assist ANZUP members with their QOL sub-studies;
- regular free training workshops about the concept of QOL and other patient-reported outcomes (PROs), and how to design and conduct QOL/PRO studies.

For more information, please visit our website: pocog.org.au/qoloffice.

We look forward to working with you over the next three years.
Correlative and Translational Research

Since the last report, a short survey of the membership was conducted. The aim of the survey was to gauge depth of interest in developing and sustaining correlative and translational research in ANZUP projects. The survey covered questions such as personal interest in this field of research, and what facilities, funding, and other capabilities individual centres were able to bring to bear to support our aims. The data are currently being collated and it is envisaged that a working group will be formed to drive projects.

In the meantime, the second Genomic Cancer Clinical Trials Initiative workshop was held on 10 October at the Stamfold Plaza Sydney Airport. Representatives from major national clinical trials groups were present, along with members of the NHMRC clinical trials centre. Whilst no funding was put on the table, some progress was made, and a few specific projects were discussed in some detail. It was apparent that these still need some work, and it appeared unlikely any of them would be “grant-ready” by March 2015 for the NHMRC round. Nevertheless, the aim of the initiative was to reach out to the multiple clinical trials groups to see if there was common ground in regards to genomic and biomarker projects that could be implemented together. In that regard, it seems as if all the clinical trials groups are keen to pursue these ideas further.

PAUL DE SOUZA
Chair, Correlative and Translational Research Committee

Consumer Advisory Panel (CAP)

Well another year has almost flown by and since my August report the CAP has been relatively quiet.

A few more articles have been provided by CAP members for the 2nd Edition of the Consumer Newsletter. We are really looking forward to reading this wonderful consumer resource that over time we hope will increase community engagement and support for ANZUP. Please remember to forward this publication onto as many of your family and friends as you can.

We have had one teleconference since the ASM in July with some excellent discussions within the group with the CAP feeling more confident to provide valuable feedback and comments. The opportunity to meet face to face annually at the ASM makes our teleconferences so much easier.

We look forward to participating in the disease specific teleconferences and to hear about new concepts being bought forward following the recent concept development meetings held in November. Ray Allen and I were very excited to volunteer at the inaugural Below the Belt Pedalthon in September. Tony Sonneveld registered a team of family and friends and bravely rode the track himself. Congratulations to all involved on such a success and look forward to 2015!

We are planning to appoint a Deputy Chair for the CAP, as has been done across the other sub-committees and this will be one of the priorities for early 2015.

And of course the planning will begin for the CAP education session to be held on Sunday 12 July. As always this session will consist of informative and relevant presentations from the CAP’s perspective.

On behalf of the CAP we thank the ANZUP Board, Marg, Liz, Jenni and Yi for their support and we wish everyone a lovely festive break with family and friends. Here’s to 2015.

BELINDA JAGO
Chair, Consumer Advisory Panel

MERRY XMAS!
ANZUP/PoCoG Fellowship ACORD Workshop

I had the privilege to attend the biennial Australia and Asia Pacific Clinical Oncology Research Development (ACORD) workshop this year, one of three initiatives of its kind worldwide. The ACORD workshop provides a week-long program focusing on clinical trial design and allows participants to develop a trial protocol under the mentorship of an international expert faculty.

This year's workshop was held at Magenta Shores, against the sunny backdrop of the northern New South Wales beaches. During the one and a half hours bus trip from Sydney to the workshop, I wasn't sure what to expect or who I might know, but once there it was great to see some familiar faces and also meet new people from diverse backgrounds but with a shared common interest in oncology and research.

The workshop was intensive. The educational and protocol development sessions, networking opportunities, one-on-one sessions to meet faculty members and occasional social events meant that there was hardly a spare moment to relax. The protocol group sessions allowed participants to explore and develop their trial concepts in a small interactive group under the mentorship of faculty members who were more than willing to share their abundant knowledge and research experience with us. My trial concept at the workshop outlined a study examining the cost-effectiveness of a collaborative model of hospital care for older cancer patients, integrating geriatric medicine concepts into an oncology ward. It is a long-term project and I know it is significantly enhanced as a result of my participation in the ACORD workshop. I thank my mentors for their patience, guidance and generous assistance; and for helping take the trial from concept to protocol in brief space of one week.

On my final day, I made it a point to wake up early to walk on the beach (at least once!). The walk was peaceful, with the calming sound of the waves and the occasional seagull. The lack of workshop participants on the beach was probably testimony to the intense workshop schedule and the extent the workshop continued to hold the interest of the participants.

I am very grateful for ANZUP and PoCoG for the generous fellowship that made it possible for me to attend the ACORD workshop and learn from a wide range of experts from different background. I left the workshop with new-found skills on clinical research and an enthusiasm to explore and develop clinical trial concepts. The workshop is an incredible resource that accelerates the development of clinical trials and I would recommend it to any clinical cancer researcher.

DR KHENG SOO
ACORD 2014 Participant

Before attending the Australia and Asia Pacific Clinical Oncology Research Development (ACORD) workshop, I’d heard a lot of seemingly conflicting stories. How could something that reportedly required you to work harder, sleep less, and consume more coffee than you ever had before also be a wonderfully educational, fantastically inspiring, and potentially career defining experience?

Having been through the wringer and come out the other side I can confirm that ACORD does somehow manage to achieve all these things, and I think it’s largely because of the people that take part. Lead by the indefatigable Martin Stockler, the faculty at ACORD were not only some of the brightest minds in their field, they were also incredibly approachable and committed to helping participants get the most out of their experience. The amount of feedback on my protocol I received between the hours of midnight and 5am is testament to their dedication. Interacting with a diverse group of participants, from variety of cultural backgrounds and oncological disciplines, but all with the common goal of conducting good research aimed at improving the lives of those affected by cancer, was similarly energizing.

The original concept that I took to ACORD, a phase-II randomised controlled trial of the potential efficacy of an online psychological intervention (e-TC) developed and piloted with seed funding from Sydney Catalyst and Cancer Council Australia was summarily dismantled on the first day. However, during over the next five days I learnt an astonishing amount about cancer research and my ego...
and concept were rebuilt. I now feel like I have the research skills, contacts, and project to make a successful start to my research post-doctoral research career. I am incredibly grateful to ANZUP and PoCoG for awarding me one of the inaugural ACORD fellowships that enabled me to attend the workshop.

BEN SMITH
ACORD 2014 Participant

Concept Development Workshops (CDW)

A new initiative for ANZUP in 2014 was the successful introduction of two Concept Development Workshops (CDW), recently held in Sydney. CDWs had been used successfully by the ANZ Germ Cell Trials Group (one of ANZUP’s forerunners) to initiate and develop trial concepts that subsequently resulted in successful clinical trials.

There are 3 major components to the CDWs:

1) All members are invited to submit a brief concept to be considered for discussion at the CDW. The aim is to encourage members to consider new proposals and submit an idea. This can be helpful for concepts that require broad feedback or further refinement. Younger members can also find this process rewarding.

2) Presentation of submitted concepts to a multidisciplinary group at the CDW including senior investigators, statisticians and CTC staff. The resulting discussion is often wide-ranging but aims to define clear “next steps”, which might include forming a working party to create a protocol or re-defining the concept with the help of newly identified collaborators.

3) An opportunity for the assembled group to brainstorm – considering gaps in current knowledge and new opportunities.

The first workshop was held on November 5th, with a Prostate Cancer Session in the morning and the afternoon was devoted to Testicular Cancer. Scott Williams chaired the Prostate Cancer Session, which included presentations from Cynthia Hawks and Carmel Pezaro. Ben Smith and Ben Tran presented proposals to the Testicular Cancer Session, which was chaired by Peter Grimison.

The second workshop was held on November 21st. Steve McCombie and Andrew Weickhardt presented their concepts in the morning Bladder Cancer Session, chaired by Dickon Hayne. Ian Davis chaired the afternoon Renal Cancer Session, which heard concepts from Craig Gedye and Nicola Lawrence.

The CDWs are not intended to replace existing opportunities to submit a concept to any of the sub-committees nor the brain-storming sessions held at the ASM. Rather, we hope that the CDWs will offer additional opportunities for concept development and encourage participation from the breadth of our membership. We hope to hold CDWs again in 2015, potentially as an annual event, and would welcome feedback about how they could be improved.

GUY TONER
Deputy Chair, ANZUP

Upcoming 2015 Events

Mark them in your diary now!

February 26-28 – Genitourinary Cancers Symposium
http://gucasym.org/about-meeting

March 24-26 – TROG

April 11-14 – USANZ ASM

May 17 – Sydney Half Marathon fundraiser
http://www.smhhalfmarathon.com.au

July 12-14 – ANZUP ASM

Sept 1 – Below the Belt Pedalthon fundraiser