



ANZUP Cancer Trials Group Limited

2010 Annual Report

The Directors of ANZUP Cancer Trials Group Limited ("ANZUP") are pleased to submit the Annual Report for 2010.

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ANZUP Cancer Trials Group Limited
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Background

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP Cancer Trials Group Ltd, "ANZUP") became a company limited by guarantee on 9 October 2008. The official launch of ANZUP was held on 20th March 2009 in Sydney.

ANZUP was formed by the merge of the Australian Prostate and Urogenital cancer Group (APUG) and the Australian and New Zealand Germ Cell Trials Group (ANZGCTG). APUG was formed as a national cooperative clinical trials group encompassing all urologic cancers (prostate, kidney, bladder/urothelial, testis and other related tumours). The aim of APUG was to bring together multiple professional disciplines and interested people to perform high quality clinical trials in urologic cancers, and to promote the systematic collection of data and tissues and facilitates basic and translational research in relation to clinical trials. ANZGCTG was a long established network of over 100 clinicians and researchers and was at the time the only national organisation dedicated to high-quality clinical research for people affected by germ cell cancers. It was the lead collaborative group for testicular cancer trials in Australia and New Zealand.

The vision of ANZUP is to minimise the effect of prostate and other urogenital cancer on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support.

The mission of ANZUP is to conduct and promote cooperative clinical trials and psychosocial research in prostate and other urogenital cancers.

The object of ANZUP is to develop, foster and promote prostate and urogenital cancer research by:

- providing access to clinical trials for all appropriate Australian and New Zealand patients
- increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research
- providing opportunities for clinical research
- building systems to simplify and streamline clinical research of the highest quality
- fostering a culture of research amongst all clinicians involved in the care of patients with urogenital cancers
- providing training opportunities for the next generation of clinical researchers
- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies

Funding for APUG was initially derived from a grant from the Victorian Cancer Agency. Subsequently funding was secured from Cancer Australia to support the merge of APUG and ANZGCTG. ANZUP was awarded ongoing funding from Cancer Australia through its Support for Clinical Trials program from January 2009 until 30 June 2010. This grant is administered through the University of Sydney (USYD) and funds for infrastructure support for ANZUP are disbursed through a separate agreement between ANZUP and USYD.

Governance structure and succession planning:

ANZUP has established a robust governance and organisational structure as outlined in Attachment 1 and in the Terms of Reference (Attachment 2). The ANZUP Constitution has been circulated separately and is proposed to be amended prior to the Annual General Meeting.

- Board. The Board comprises the Directors of the Company and is responsible for financial management, corporate governance, reporting and compliance. The Board consists of four elected Directors (one position currently vacant), and Executive Director (vacant). The Board also has the power under the ANZUP constitution to appoint up to two appointed Directors, but the Board has not exercised this power at this stage. The Board meets by teleconference approximately once per month and face-to-face several times per year.
- Secretariat. The secretariat comprises an Executive Officer and a Project Officer. As at June 2010 both these positions are vacant but are expected to be filled in the near future. The company's registered office is located in Sydney.
- Operations Executive Committee. This committee consists of representatives from ANZUP and from the NHMRC Clinical Trials Centre at University of Sydney. The Committee is responsible for oversight of trial and group operations. This Committee meets by teleconference approximately once per month.
- Scientific Advisory Committee (SAC). The SAC consists of a core of members representing the major disciplines relevant to ANZUP, nominated and appointed upon the recommendation of those groups. In addition, chairs of the SAC subcommittees are members of the SAC by virtue of their appointment as Chair. The SAC meets by teleconference quarterly and face-to-face at least once per year.
- SAC subcommittees. The SAC is advised by disease-specific subcommittees (Prostate; Renal; Germ Cell; Bladder) and non-disease-specific subcommittees (Quality of Life & Supportive Care; Correlative and Translational Research). The disease-specific subcommittees are responsible for oversight of trials within their portfolios, as well as development of new trial concepts. These subcommittees meet by teleconference quarterly and face-to-face at least once per year. The non-disease - specific subcommittees are involved as required in trial development and management in order to ensure that maximum value is added to every trial. These subcommittees meet by teleconference as required and face-to-face at least once per year.
- Consumer Advisory Panel (CAP). The CAP comprises consumer/community representatives who advise ANZUP at all levels of governance, from the Board through to specific trials and research projects. The CAP also provides a conduit for communication from ANZUP back to the community in order to promote research and engage community support. The CAP meets by teleconference as required and face-to-face at least once per year.
- Independent Data Monitoring Committee. The IDMC is yet to be established but terms of reference have been drafted. It is anticipated that the IDMC will have oversight of multiple clinical trials.
- Trial Management Committees. Each trial has a TMC that meets approximately quarterly by teleconference to ensure oversight of the trial.

Clinical trial activities and operations

Current Trial Activity:

Germ cell:

- Accelerated BEP phase 2 (ANZGCTG 0206/ANZGOG 0603). This study examines the feasibility of two-weekly BEP chemotherapy. Presentations of this work have been made at ASCO, ASCO GU, and the Asian Oncology Summit. 39/45 patients registered (87% of revised target), with 14 activated Australian Sites.
- Chemo & Cognition. This study evaluates the effect of chemotherapy of cognitive function, using men with testicular cancer not receiving chemotherapy as the control group. 93/154 patients have been registered (60% of target), with 11 activated Australian Sites and one activated NZ Site.
- Aprepitant antiemetic study. This trial is supported by MSD and examines the use of prolonged treatment with aprepitant in the context of chemotherapy administered over five days. 30/50 patients have been registered (60% of target), with 9 Australian activated sites. One new site is currently in the process of activation.
- Survivorship study + EORTC QLQ-TC26 (POCOG). This intergroup study is being run with PoCoG and examines survivorship issues in men with testicular cancer. On 19th May 2010, 118/250 survivors (47% of target) had been accrued.
- Good prognosis study. This study, which was initiated by ANZGCTG before the merger, continues to follow patients.

RCC:

- SORCE (RE-05). This intergroup study is being run through MRC UK and multiple European groups. It examines the activity and duration of treatment with adjuvant sorafenib in patients with resected RCC at intermediate or high risk of recurrence. The study includes the TRANSORCE tissue substudy and the PAS Preferences substudy. The ANZUP Correlative and Translational Research subcommittee is involved in developing laboratory assays for use in TRANSORCE. SORCE is supported in part by funds from Bayer Australia. PAS is being led internationally by ANZUP and an application for grant funding through Cancer Australia has been made. 24/250 patients randomised (10% of target), with 18 activated Australian Sites. Four new sites are currently in the process of activation.
- EVERSUN. This protocol was developed by the ANZUP RCC subcommittee and will examine whether alternating sunitinib/everolimus as first line therapy is feasible and active, with a view to a subsequent randomised study to compare this regimen with sequential use of study drugs. Tissue-based substudies are under development through the Correlative and Translational Research subcommittee. EVERSUN is supported by funds from Novartis. 14 sites are planned for Australia.

Prostate:

- RAVES. This is an intergroup study being run with TROG and USANZ. It compares adjuvant with salvage radiotherapy in men with high risk resected prostate cancer. On the 20th May 2010, 79/470 patients had been recruited (17% of target).

Proposed studies and protocol development. These trials will require specific funding resources before they can proceed.

Prostate:

- START. This study is being run through NCI Canada and compares watchful waiting with definitive early intervention in low risk prostate cancer. grant applications have been submitted to Cancer Australia and to the Prostate Cancer Foundation Australia.
- PC4 follow up study. This study is planned to be run as an intergroup study with PC4. It will examine the feasibility of followup of prostate cancer through their general practitioners.

RCC:

- None currently planned.

Germ cell:

- Accelerated BEP phase 3. This trial is currently in planning and will involve international cooperative clinical trials groups.

Bladder:

Superficial bladder cancer. A study looking at the use of BCG and Mitomycin C in superficial bladder cancer is under development.

Other activities

Data and quality:

Cancer Australia-supported trials staff at NHMRC Clinical Trials Centre have continued to contribute to the update and maintenance of group-specific Standard Operating Procedures (SOPs) to reflect relevant quality standards (GCP ICH) and relevant regulatory guidelines. All trials staff is qualified by education and are trained in SOPs, consistent with GCP guidelines and the National Statement on Ethical Conduct in Human Research (2007) and have implemented these processes on ANZUP trials.

Databases for the Aprepitant Trial, PAS in SORCE sub-study, and Accelerated BEP Trial have been designed and tested for release by the appointed data systems developer and programmer in the reporting period using the systems 'InForm' and 'ClinTrial' . ANZUP appointed staff at NHMRC Clinical Trials Centre have also contributed to the development of e-CRFs and database systems for future trials, such as the proposed phase III RCT of Accelerated BEP, including the review of existing data management SOPs. The systems developed for these processes include interactive real time and batch queries, a complete audit trail, and reporting functions. In addition, clinical trials staff assigned to ANZUP have undertaken training modules to ensure the optimal management of clinical trials data by all staff using these systems.

Fundraising:

A fundraising initiative ("Dinner with the Doctor") was held during 2009.

Group meetings:

- An ANZUP scientific meeting was held in Sydney on 1 December 2008.
- The ANZUP launch was officially held on 20 March 2009 in conjunction with the launch of the SORCE trial.
- The first ANZUP Annual Scientific Meeting was held on the Gold Coast on Friday 20 November 2009.

- An initiation launch for EVERSUN was held on the 19th March 2010 with attendance from approximately 35 site staff, including investigators from around Australia.
- The 2010 ANZUP Annual Scientific Meeting is planned to be held in Melbourne on Friday 12 November 2010.
- Regular meetings of the Board, Operations Executive, SAC, SAC subcommittees, CAP and Trial Management Committees have been held as described above.

Web Site and communication:

The ANZUP web site www.anzup.org or www.anzup.org.au was launched and is currently accessible. The tools expected to be available to modify the web site have unfortunately not been available and the site is currently inactive. The Board has engaged a new web site developer and the process of redesign of the site is well underway.

One edition of the newsletter “UPDate” has been circulated. Other communication with the group has been through meetings, teleconferences and emails.

Group Membership:

As at 1 June 2010, ANZUP had 136 members covering a wide range of professional disciplines. In February 2010 the breakdown of membership was as follows:

Medical Oncology:	43
Urologic Surgery:	15
Radiation Oncology:	18
Nursing:	6
Psycho-Oncology:	4
Supportive care	2
Consumer Advocacy:	4
Biostatistics:	4
Clinical Epidemiology:	3
Scientists:	13
Pathologists:	5
Trial coordination and management:	5
Nuclear medicine	1
General practice	1

Number of members by State/Territory (February 2010):

ACT:	4
NSW:	47
NT:	0
QLD:	15
SA:	9
TAS:	1
VIC:	30
WA:	7
New Zealand:	5
Overseas:	6

Strategic and business planning:

The Board has developed a Strategic Plan for 2010-2012 (attachment 3). Part of the plan involves identification and appointment of Directors with expertise in legal, corporate, accounting and fundraising issues. Other key objective are to continue to build research capacity, extend collaborations and to mentor young investigators.

Changes in state of affairs

An elected Director (Pamela Russell) and the Executive Director (John Ramsay) resigned from the Board in early 2010.

In accordance with section 8.13(a) of the ANZUP Constitution, Guy Toner and Lizbeth Kenny must resign as elected Directors but are eligible to be re-elected.

The Board recommends changes to the composition of the Board which will come into effect if the members pass the special resolution to amend ANZUP's constitution which will be considered at the extraordinary general meeting (EGM) scheduled to be held on Friday 25 June 2010 at 12:30pm to 1:15pm. Details of the proposed amendments to the ANZUP constitution are set out in an explanatory memorandum attached to the notice of meeting for the EGM.

The Board was not able to hold the first ANZUP Annual General Meeting in accordance with the usual requirements of the *Corporations Act 2001* (Cth) because the company audit was not able to be completed by that deadline. An application was made to ASIC to extend the time by which ANZUP may hold its first AGM to 30 June 2010 pursuant to *s.250P of the Corporations Act 2001*. This application was granted. The first Annual General Meeting (AGM) of ANZUP will be held on Friday 25 June 2010 at 1:15pm to 3:00 pm (AEST).

Matters affecting ANZUP operations and state of affairs in future financial years

At the time of preparation of this report, approval of recurrent funding from Cancer Australia under its Support for Clinical Trials scheme had not yet been confirmed. This funding will be critical for the future operations of ANZUP.

Additional funding sources will need to be identified in order to support the proposed expansion of activities of ANZUP.

Likely developments in operations and expected results

ANZUP plans to employ an Executive Officer and a Project Officer. Further expansion in staff may be necessary depending on the scope of activities. This will only be possible with additional funding. ANZUP plans to continue to develop clinical trials and aims to activate 1-2 new protocols per year.

ANZUP Directors

Director	Role	Appointed	Resigned	Board meetings	
				Eligible	Attended
Ian Douglas Davis	Chair; Public Officer from 14 April 2010	9 Oct 2008	N/A	19	18
Guy Campbell Toner	Deputy Chair; Company Secretary from 16 Feb 2010	9 Oct 2008	N/A	19	16
Lizbeth Moira Kenny	Treasurer	9 Oct 2008	N/A	19	14
Pamela Joan Russell	Company Secretary until 5 Feb 2010	9 Oct 2008	5 Feb 2010	16	13
John Douglas Ramsay	Executive Officer and Public Officer until 13 Apr 2010	9 Oct 2008	13 Apr 2010	16	12

Experience of Directors:

A/Prof Ian Davis MB BS PhD FRACP FACHPM is a medical oncologist working at Austin Health and the Ludwig Institute for Cancer Research (LICR) in Melbourne, where he is Head of the Uro-Oncology Laboratory. He holds a Victorian Cancer Agency Clinical Researcher Fellowship and is an NHMRC Honorary Practitioner Fellow. His primary clinical interests are in urologic cancer and melanoma, and his primary research interests are in cancer immunology and the biology of urologic cancers. A/Prof Davis is a member of the Cancer Council Victoria Urology, Skin, and Medical and Scientific Committees.

Associate Professor Guy Toner MBBS MD FRACP is a graduate of the University of Melbourne. He undertook sub-specialty training in medical oncology at the Alfred Hospital before spending three years at Memorial Sloan-Kettering Cancer Center in New York, where he worked in the GU Service. He developed a special interest in testicular cancer while in New York and his research there formed the basis of his MD thesis. He returned to Melbourne to take up a full-time position at Peter MacCallum Cancer Centre in 1990. His clinical and research interests include all urological cancers and he also has an interest in new drug development. He was Chair of ANZGCTG since 1995.

Dr Liz Kenny MB BS FRANZCR FACR graduated in Medicine from The University of Queensland in 1980, and completed her specialty training in Radiation Oncology at The Queensland Radium Institute in Brisbane in 1987. Liz is a Senior Radiation Oncologist at The Royal Brisbane & Women's Hospital. In 2005 she was appointed as Medical Director, Cancer Services, Central and is committed to improving Cancer Services in Queensland. Her main areas of specialty interest are Head and Neck Cancer, Breast Cancer and Urological Malignancies.

Prof Pamela J Russell AM PhD, Conjoint Professor of Medicine, is a cancer biologist and immunologist who has been the Director of the Oncology Research Centre in the Prince of Wales Clinical School at the University of New South Wales. She now holds a position at the Institute of Health and Biomedical Innovation, Queensland University of Technology. Her laboratory has an international reputation for establishing rare human bladder and

prostate cancer cell lines and xenografts and for performing preclinical studies. Her major current interests are in the use of nanotechnology for enabling imaging of prostate cancer, and for delivery of gene therapy for late stage disease. She has been part of a team with CSIRO that has developed a targeted gene therapy for prostate cancer that is to go to clinical trial in the near future, and which received a platinum nomination for the CSIRO Chairman's medal in 2003. She helped to initiate and was an inaugural director of the Prostate Cancer Foundation of Australia, of which she has been made a life member. She was awarded an AM for her contributions to prostate and bladder cancer research in 2003, a prize for outstanding research alumni of the Kolling Institute at their 75th anniversary in 2006, and was Member of the year for Marquis' Who's Who in 2007. Pamela is an accredited member of the Australian Institute of Company Directors

Dr John Ramsay PhD has worked in primary care and men's health for the past 25+ years both in Australia and overseas. He was trained in forensic psychotherapy and undertook doctoral research in psychology at the University College London (UCL). This included new investigative work into the interpersonal psychological processes leading to psychiatric morbidity in children and adolescents – and in self-harming adolescents. He has worked for the Prostate Cancer Foundation of Australia, the Urology Oncology Program NSW (Cancer Institute NSW) and the NSW Cancer Council. John is an accredited member of the Australian Institute of Company Directors.

Officers indemnity and insurance

Rule 14 of the ANZUP Constitution reads as follows:

14.1 INDEMNITY

Subject to the Act, the Company must, to the extent the person is not otherwise indemnified, indemnify every officer (as defined in the Act) of the Company and may indemnify its auditor against a liability:

(a) incurred, in their respective capacities, to the Company, to a related body corporate or to a person other than the Company (including a liability incurred as a result of appointment or nomination of the Company or subsidiary as a trustee or as an officer of another corporation) unless the liability arises out of conduct involving a lack of good faith or is for a pecuniary penalty order or compensation under the Act, and

(b) for costs and expenses incurred by the officer or auditor in defending civil or criminal proceedings in which judgment is given in favour of that person or in which that person is acquitted, or in connection with an application in relation to those proceedings in which the court grants relief to that person under the Act.

14.2 INSURANCE

Subject to the Act, the Company may enter into and pay premiums on a contract of insurance in respect of any person, to the fullest extent permitted by the Act.

The premium for Directors' Insurance is \$1000 per annum.

Auditor

ANZUP's auditor is Moore Stephens.

Financial report

The financial report contains additional information included to give a true and fair view of ANZUP's financial position and performance. The Directors are of the opinion that the inclusion of this information was necessary to give this true and fair view, on the recommendation of the Auditor.



IAN DOUGLAS DAVIS

4 JUNE 2010

Signed (Director)

Printed name

Date of signature

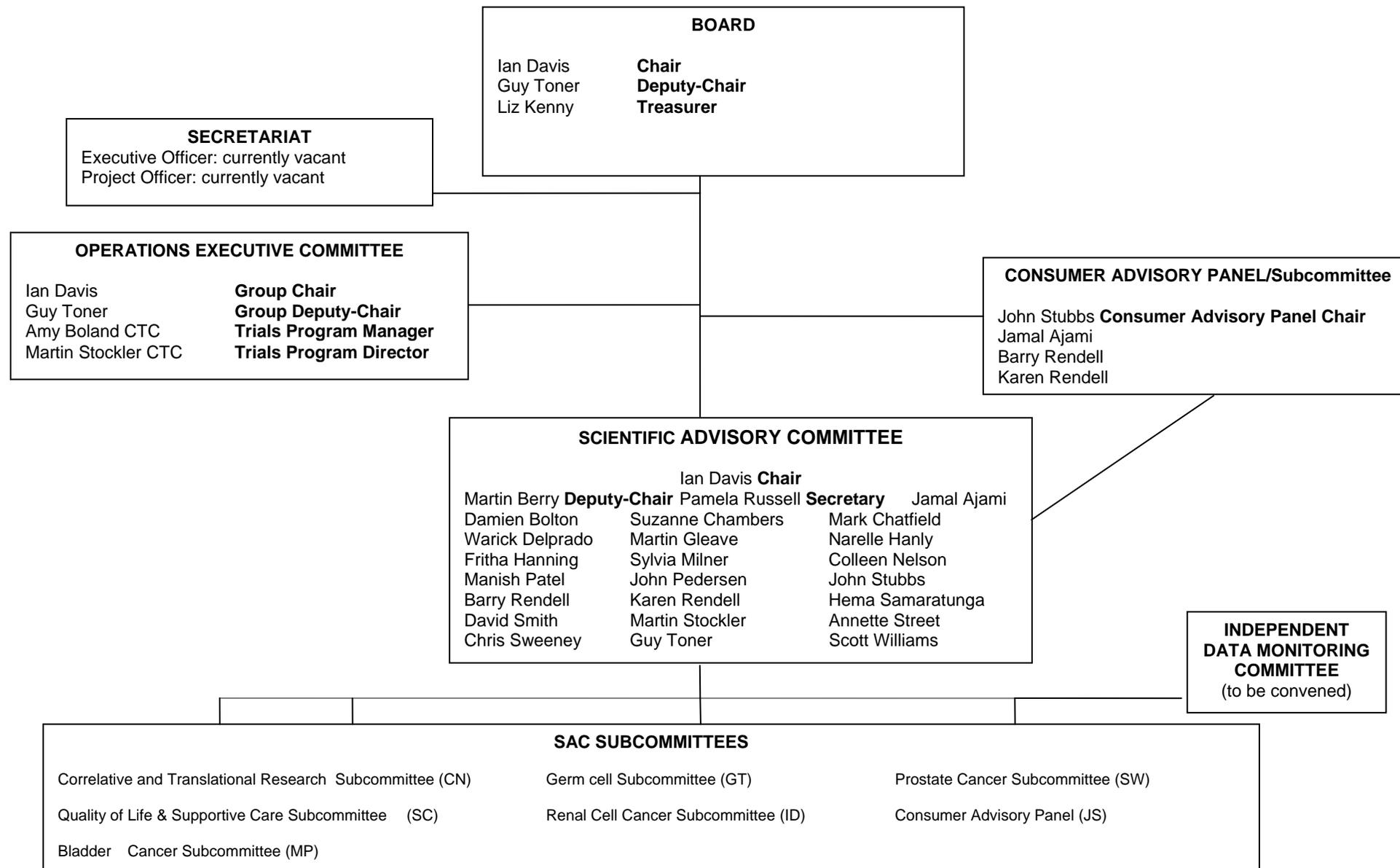
Attachments:

1. Governance/organisational chart
2. Terms of Reference and Standard Operating Procedures
3. ANZUP Strategic Plan 2010 - 2012

Attachment 1: ANZUP Governance Structure / Organisational Chart

ANZUP Organisational Chart

4 June 2010



CN- Colleen Nelson

GT-Guy Toner

ID-Ian Davis

JS-John Stubbs

MP-Manish Patel

SC-Suzanne Chambers

SW-Scott Williams

Attachment 2: Terms of Reference and Standard Operating Procedures

VERSION 1.0
9 NOVEMBER 2009



TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

ANZUP Cancer Trials Group Limited

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Web www.anzup.org.au

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The purpose of the ANZUP Cancer Trials Group Ltd Scientific Advisory Subcommittees is to provide a mechanism for the development of new trial proposals, prioritisation and incorporation of key translational and research questions into active and proposed trials including the monitoring of ongoing trials and establishing research priorities. The Disease and cross-disease specific subcommittees should aim to address the object of ANZUP objectives as described in the Company SOP's. The ANZUP Cancer Trials Group Strategic Plan stipulates that the Subcommittee should consider ways to develop, foster and promote prostate and other Urogenital cancer research by aiming to:

ANZUP will foster the vision and mission of the Company by aiming to minimise the effect of prostate and other urogenital cancers on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support and will conduct and promote cooperative clinical trials and psychosocial research in prostate and other Urogenital cancers.

The object of ANZUP is to develop, foster and promote prostate and other urogenital cancer research by:

- Filling a niche in Australia and New Zealand in answering clinical questions that are currently not addressed by industry-sponsored or other clinical trials
- Finding ways to create strong links with Cancer Australia and/or other peak bodies aiming to explore and initiate trials in under-researched areas.
- Providing access to clinical trials for all appropriate Australian and New Zealand patients
- Increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research
- Providing opportunities for clinical research
- Building systems to simplify and streamline clinical research of the highest quality
- Identifying strategies for inclusion of functional imaging studies in ANZUP trials
- Promoting systematic collection of tissue and data on trial participants and in general genitourinary oncology clinical practice
- Addressing specific health and medical issues of culturally and linguistically diverse groups and Aboriginal and Torres Strait Islanders by identifying if there is a need to facilitate better clinical and laboratory research in these populations and to develop protocols in such areas.
- Providing training opportunities for the next generation of clinical researchers through access to clinical and scientific for a, basic research and clinical trials.

Status within the Organisation

The Scientific Advisory Subcommittee is a subcommittee of ANZUP and is established by the Scientific Advisory Committee (SAC) and the Board of Management.

Structure

All subcommittees function under the direction of the ANZUP Cancer Trials Group[Scientific Advisory Committee. The core composition of the subcommittee will reflect the mix of professionals across disciplines.

The subcommittees will be managed by a Chair with support from the ANZUP Executive Officer and secretariat as required.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Responsibilities

Disease Specific Subcommittees

(Prostate Cancer Subcommittee, Bladder Cancer Subcommittee, Germ Cell Cancer Subcommittee and Renal Cell Cancer Subcommittee)

The primary focus of the Disease Specific Subcommittees is the identification of research need in the area of each subcommittee disease area and the generation of clinical trial concepts from the subcommittees' disease perspective.

Each disease specific subcommittee will assess and develop research strategies with a strong scientific justification, in accordance with the vision, mission and values of the ANZUP vision (Appendix 1), keeping within ICH Guidelines for Good Clinical Practice and the Australian National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) or successors. In addition, ongoing reviews of the International Literature will be performed aimed at prioritizing the disease specific issues in Urogenital and Prostate Cancer for future research as well as preparation of written and oral reports of the subcommittee's trials.

Key activities for all disease specific subcommittees include involvement of the non-disease specific subcommittees (Consumer Advisory Panel (CAP), Quality of Life & Supportive Care Subcommittee and Pathology Tissue & Ethics Subcommittee). The CAP may be involved in the development and review of clinical trial concepts from the consumers' perspective and other activities including advising on ways to increase the public profile/awareness of genitourinary cancers and the importance of clinical trials in the specific subcommittee disease area.

Cross-Disease Subcommittees

(Quality of Life and Supportive care, Correlative and Translational Research Subcommittee and Consumer Advisory Panel)

The role of Scientific Advisory Cross-Disease Subcommittees is to provide support and input into protocol design and management with respect to each subcommittee's area of interest. These Subcommittees are to be engaged in early processes of protocol development. The meetings of the cross-disease subcommittees are to be held as required to meet the needs for development or use of current protocols.

Quality of Life and Supportive care

Quality of life and supportive care subcommittee will advocate appropriate inclusion of health-related quality of life (HRQoL) endpoints as well identifying instances where a protocol has included HRQoL unnecessarily. The HRQoL measures (effects of disease and treatment as perceived and reported by patients, caregivers and families) will be provided to SAC and other disease specific subcommittees on an ad hoc and trial basis with regard to:

1. Research direction and priorities relating to the health-related quality of life of patients, caregivers and families;
2. The need for inclusion of health related quality of life endpoints on a trial by trial basis;
3. The consistent, appropriate, valid and rigorous assessment, analysis and interpretation of health-related quality of life across all ANZUP Cancer Trials Group trials;
4. Ongoing review of the international literature aimed at prioritising health-related quality of life issues in prostate and urogenital cancers for future research.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

In general, inclusion of an HRQoL endpoint should be considered by the Scientific Advisory Committee, Trial Management Committee and disease specific subcommittees whenever:

- A new (invasive) treatment is being evaluated;
- Different treatment modalities are being compared;
- Treatments of different intensity or duration are being compared;
- Treatments are expected to be of similar efficacy (e.g. terms of survival);
- The intent of treatment is palliative;
- Adjuvant therapies for patients at low risk of recurrence of disease are being compared;
- Treatments differ in short term efficacy but the overall failure rate is high; and
- Treatments may have long-term negative effects on Quality of Life for survivors.

Correlative and Translational Research Subcommittee

The Correlative and Translational Research Subcommittee will give guidelines or pathology review within trials, assist in the development of translational research particularly in the context of ANZUP Cancer Trials Group clinical trials. It will advise the ANZUP Cancer Trials Group Scientific Advisory Committee and other Subcommittees regarding translational research and incorporation of basic science into clinical research protocols.

Correlative and Translational Research Subcommittee aims to identify relevant biological factors enabling identification of prognostic factors of patient subgroups responding to the treatments tested, understanding of the respective underlying molecular mechanisms, and discovery of new molecular targets for future therapies.

Correlative and Translational Research Subcommittee should be considered for all ANZUP Cancer Trials Group clinical trial protocols. Correlative and Translational Research Subcommittee will generate research questions applicable to each proposed protocol, including relevant study endpoints.

Consumer Advisory Panel

The ANZUP Cancer Trials Group Limited Consumer Advisory Panel/Committee (CAP) provides a mechanism for advice to be offered on specific studies, general research directions, and priorities from a consumer perspective on an ad hoc basis.

Key activities proposed include review of specific clinical trial concepts from the consumers' perspective including validity of overall trial questions and comments and suggestions regarding the protocol, lay summary, Patient Information and Consent Form (PICF) and other issues as requested.

Members of the CAP may also become involved in other activities including advising on ways to increase the public profile/awareness of urogenital cancers and the importance of clinical trials in this area. The primary focus of the panel will be on the scientific activities outlined above but involvement in broader activities could be considered by the CAP in consultation with the Board of Management.

For full Consumer Advisory Panel Terms of Reference, refer to ANZUP Cancer Trials Group Consumer Advisory Panel/Consumer Engagement Document.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Advice on Measures

Collaboration with and advice from the non-disease specific subcommittees and others within ANZUP Cancer Trials Group and NHMRC Clinical Trial Centre (where appropriate) will contribute to more consistent assessment, analysis and interpretation of measures across all cancer trials within ANZUP Cancer Trials Group. Advice will be given in accordance with national guidelines relating to:

- Sample size and eligibility criteria for inclusion in each subcommittee's sub-studies;
- Choice of patient-reported outcome measures;
- Timing assessment in each trial;
- Mode of delivery and appropriate use of proxy raters;
- Procedures for collecting insert subcommittee specialty data, with an emphasis on maximising compliance;
- Ways of handling missing data analysis;
- Reporting of each subcommittees results.

Each disease specific and non-disease specific subcommittee will provide an annual report to the SAC summarising its activities as well as attending ANZUP Cancer Trials Group Annual Scientific Meeting.

Appointment of Members and Terms of Appointment

The term of appointment is 2 years. Any member of ANZUP is eligible to be a member of subcommittee and is eligible to be a member of more than one subcommittee. Any subcommittee member is eligible to stand for nomination for Chair or Deputy Chair of the subcommittee. Participation is voluntary and expenses will be reimbursed by ANZUP for Subcommittee-related activities.

The role of the subcommittee Chair is to provide leadership and promote participation in the activities of the subcommittee and within ANZUP more broadly. The Chair and Deputy Chair of each subcommittee are appointed by the ANZUP Board on advice from the SAC. The Chair will be a member of the SAC by virtue of the appointment. The Deputy Chair or other SAC member may act as proxy to represent the Chair should the Chair be unable to attend.

The Chair and Deputy Chair appointments will be for a period of three years, with the possibility of an extension for three years. At the end of two terms of appointment, before a member can reapply for a further term in the same position, a significant period must elapse (at least one year). The method of appointment for both the Chair and Deputy Chair positions are specified in the ANZUP cancer Trials Group SOP's (point 1-2; 1-3 respectively).

ANZUP members wishing to join a subcommittee must submit details as follows to the Chair of the subcommittee:

1. Their experience of urogenital cancer/s;
2. Their experience of clinical trial participation (if any);
3. Their involvement with other consumer groups;
4. Their reasons for wishing to join the subcommittee;
5. Whether they are willing to be involved in the promotion of clinical trials research;
6. Their resumé.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Essential Criteria

The essential criterion for a member of the Scientific Advisory Subcommittees their commitment to clinical trials as a key strategy for improving the outcomes of those affected by genitourinary cancer. This includes supporting and promoting every person's right to information concerning trials and their right to make a personal, informed choice. Their role is a function within the Scientific Advisory Subcommittee and will be under the direction of the Subcommittee Chair.

Expectations of Members

It is recognised that Subcommittee members will be functioning within the subcommittee on a voluntary basis with professional and family commitments; however, all Subcommittee members are asked to be aware of responsibilities involved regarding their participation in the subcommittee activities and meetings. Members may be given opportunities to participate in National and international meetings including participation in ANZUP Cancer Trials Group presentations. Members will be acknowledged in ANZUP Cancer Trial Group's annual report and associated publications. Availability to attend and/or give presentations at other relevant meetings, forums and conferences is desirable. Members' timely responses to various proposals, protocols and documents will also be sought throughout the year.

All new subcommittee members are also required to sign a Confidentiality Undertaking and are furnished with:

1. ANZUP Cancer Trials Group Scientific Advisory Subcommittee Terms of Reference;
2. Member contact details;
3. Recent Subcommittee meeting minutes;
4. Relevant ANZUP operational and personnel information;
5. Lists of ANZUP Clinical Trials;
6. Any other pertinent information.

Meetings

The disease specific Subcommittee's (Prostate Cancer subcommittee, Renal Cell Cancer Subcommittee, Germ Cell Cancer Subcommittee and Bladder Cancer Subcommittee) should hold a minimum of 2-3 teleconferences a year and at least one face-to-face meeting to review new concepts and generate research proposals as outlined below. These meetings should preferably be held prior to the ANZUP Scientific Advisory Committee meetings in order to be able to have all proposed study concepts approved by subcommittee and submitted for SAC consideration

Non-disease specific Subcommittee's (Quality of Life and Supportive Care Subcommittee, Bioinformatics Subcommittee, Consumer Advisory Panel and Pathology, Tissue and Ethics Subcommittee) will hold meetings on an ad-hoc basis. In addition, each ANZUP Cancer Trials Group subcommittee should have representation at the ANZUP Annual Scientific Meeting. Feedback will be provided to the Board via the Executive Officer.

Recording and distribution of Subcommittee meeting minutes:

Invitation to the Subcommittee members should be sent by the Chair along with the agenda and any study concepts to be discussed. The ANZUP secretariat will organise a scribe from COGS to take minutes for all the subcommittee teleconferences and face-to-face meetings and confirm with the chair that the booking has been made. The minutes will then be sent to the subcommittee chairs by the scribe within 48 hours of the meeting and these in turn should be submitted to the ANZUP secretariat by the subcommittee chair within 24 hours of receipt.

Confidentiality and Conflict of Interest

All members of ANZUP Cancer Trials Group Scientific Advisory Subcommittee will be asked to declare all/any conflict of interest in each subcommittee meetings, and must do so in any matters considered by the subcommittee.

APPENDIX 1

Vision

The vision of the Company is to minimise the effect of prostate and other urogenital cancer on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support.

Mission

The mission of the Company is to conduct and promote cooperative clinical trials and psychosocial research in prostate and other urogenital cancers.

Object

The object of the Company is to develop, foster and promote prostate and urogenital cancer research by:

- providing access to clinical trials for all appropriate Australian and New Zealand patients;
- increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research;
- providing opportunities for clinical research;
- building systems to simplify and streamline clinical research of the highest quality;
- fostering a culture of research amongst all clinicians involved in the care of patients with urogenital cancers;
- providing training opportunities for the next generation of clinical researchers;
- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies.

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TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

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TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

The purpose of the ANZUP Cancer Trials Group Ltd Scientific Advisory Subcommittees is to provide a mechanism for the development of new trial proposals, prioritisation and incorporation of key translational and research questions into active and proposed trials including the monitoring of ongoing trials and establishing research priorities. The Disease and cross-disease specific subcommittees should aim to address the object of ANZUP objectives as described in the Company SOP's. The ANZUP Cancer Trials Group Strategic Plan stipulates that the Subcommittee should consider ways to develop, foster and promote prostate and other Urogenital cancer research by aiming to:

ANZUP will foster the vision and mission of the Company by aiming to minimise the effect of prostate and other urogenital cancers on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support and will conduct and promote cooperative clinical trials and psychosocial research in prostate and other Urogenital cancers.

The object of ANZUP is to develop, foster and promote prostate and other urogenital cancer research by:

- Filling a niche in Australia and New Zealand in answering clinical questions that are currently not addressed by industry-sponsored or other clinical trials
- Finding ways to create strong links with Cancer Australia and/or other peak bodies aiming to explore and initiate trials in under-researched areas.
- Providing access to clinical trials for all appropriate Australian and New Zealand patients
- Increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research
- Providing opportunities for clinical research
- Building systems to simplify and streamline clinical research of the highest quality
- Identifying strategies for inclusion of functional imaging studies in ANZUP trials
- Promoting systematic collection of tissue and data on trial participants and in general genitourinary oncology clinical practice
- Addressing specific health and medical issues of culturally and linguistically diverse groups and Aboriginal and Torres Strait Islanders by identifying if there is a need to facilitate better clinical and laboratory research in these populations and to develop protocols in such areas.
- Providing training opportunities for the next generation of clinical researchers through access to clinical and scientific for a, basic research and clinical trials.

Status within the Organisation

The Scientific Advisory Subcommittee is a subcommittee of ANZUP and is established by the Scientific Advisory Committee (SAC) and the Board of Management.

Structure

All subcommittees function under the direction of the ANZUP Cancer Trials Group[Scientific Advisory Committee. The core composition of the subcommittee will reflect the mix of professionals across disciplines.

The subcommittees will be managed by a Chair with support from the ANZUP Executive Officer and secretariat as required.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Responsibilities

Disease Specific Subcommittees

(Prostate Cancer Subcommittee, Bladder Cancer Subcommittee, Germ Cell Cancer Subcommittee and Renal Cell Cancer Subcommittee)

The primary focus of the Disease Specific Subcommittees is the identification of research need in the area of each subcommittee disease area and the generation of clinical trial concepts from the subcommittees' disease perspective.

Each disease specific subcommittee will assess and develop research strategies with a strong scientific justification, in accordance with the vision, mission and values of the ANZUP vision (Appendix 1), keeping within ICH Guidelines for Good Clinical Practice and the Australian National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) or successors. In addition, ongoing reviews of the International Literature will be performed aimed at prioritizing the disease specific issues in Urogenital and Prostate Cancer for future research as well as preparation of written and oral reports of the subcommittee's trials.

Key activities for all disease specific subcommittees include involvement of the non-disease specific subcommittees (Consumer Advisory Panel (CAP), Quality of Life & Supportive Care Subcommittee and Pathology Tissue & Ethics Subcommittee). The CAP may be involved in the development and review of clinical trial concepts from the consumers' perspective and other activities including advising on ways to increase the public profile/awareness of genitourinary cancers and the importance of clinical trials in the specific subcommittee disease area.

Cross-Disease Subcommittees

(Quality of Life and Supportive care, Correlative and Translational Research Subcommittee and Consumer Advisory Panel)

The role of Scientific Advisory Cross-Disease Subcommittees is to provide support and input into protocol design and management with respect to each subcommittee's area of interest. These Subcommittees are to be engaged in early processes of protocol development. The meetings of the cross-disease subcommittees are to be held as required to meet the needs for development or use of current protocols.

Quality of Life and Supportive care

Quality of life and supportive care subcommittee will advocate appropriate inclusion of health-related quality of life (HRQoL) endpoints as well identifying instances where a protocol has included HRQoL unnecessarily. The HRQoL measures (effects of disease and treatment as perceived and reported by patients, caregivers and families) will be provided to SAC and other disease specific subcommittees on an ad hoc and trial basis with regard to:

1. Research direction and priorities relating to the health-related quality of life of patients, caregivers and families;
2. The need for inclusion of health related quality of life endpoints on a trial by trial basis;
3. The consistent, appropriate, valid and rigorous assessment, analysis and interpretation of health-related quality of life across all ANZUP Cancer Trials Group trials;
4. Ongoing review of the international literature aimed at prioritising health-related quality of life issues in prostate and urogenital cancers for future research.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

In general, inclusion of an HRQoL endpoint should be considered by the Scientific Advisory Committee, Trial Management Committee and disease specific subcommittees whenever:

- A new (invasive) treatment is being evaluated;
- Different treatment modalities are being compared;
- Treatments of different intensity or duration are being compared;
- Treatments are expected to be of similar efficacy (e.g. terms of survival);
- The intent of treatment is palliative;
- Adjuvant therapies for patients at low risk of recurrence of disease are being compared;
- Treatments differ in short term efficacy but the overall failure rate is high; and
- Treatments may have long-term negative effects on Quality of Life for survivors.

Correlative and Translational Research Subcommittee

The Correlative and Translational Research Subcommittee will give guidelines or pathology review within trials, assist in the development of translational research particularly in the context of ANZUP Cancer Trials Group clinical trials. It will advise the ANZUP Cancer Trials Group Scientific Advisory Committee and other Subcommittees regarding translational research and incorporation of basic science into clinical research protocols.

Correlative and Translational Research Subcommittee aims to identify relevant biological factors enabling identification of prognostic factors of patient subgroups responding to the treatments tested, understanding of the respective underlying molecular mechanisms, and discovery of new molecular targets for future therapies.

Correlative and Translational Research Subcommittee should be considered for all ANZUP Cancer Trials Group clinical trial protocols. Correlative and Translational Research Subcommittee will generate research questions applicable to each proposed protocol, including relevant study endpoints.

Consumer Advisory Panel

The ANZUP Cancer Trials Group Limited Consumer Advisory Panel/Committee (CAP) provides a mechanism for advice to be offered on specific studies, general research directions, and priorities from a consumer perspective on an ad hoc basis.

Key activities proposed include review of specific clinical trial concepts from the consumers' perspective including validity of overall trial questions and comments and suggestions regarding the protocol, lay summary, Patient Information and Consent Form (PICF) and other issues as requested.

Members of the CAP may also become involved in other activities including advising on ways to increase the public profile/awareness of urogenital cancers and the importance of clinical trials in this area. The primary focus of the panel will be on the scientific activities outlined above but involvement in broader activities could be considered by the CAP in consultation with the Board of Management.

For full Consumer Advisory Panel Terms of Reference, refer to ANZUP Cancer Trials Group Consumer Advisory Panel/Consumer Engagement Document.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Advice on Measures

Collaboration with and advice from the non-disease specific subcommittees and others within ANZUP Cancer Trials Group and NHMRC Clinical Trial Centre (where appropriate) will contribute to more consistent assessment, analysis and interpretation of measures across all cancer trials within ANZUP Cancer Trials Group. Advice will be given in accordance with national guidelines relating to:

- Sample size and eligibility criteria for inclusion in each subcommittee's sub-studies;
- Choice of patient-reported outcome measures;
- Timing assessment in each trial;
- Mode of delivery and appropriate use of proxy raters;
- Procedures for collecting insert subcommittee specialty data, with an emphasis on maximising compliance;
- Ways of handling missing data analysis;
- Reporting of each subcommittees results.

Each disease specific and non-disease specific subcommittee will provide an annual report to the SAC summarising its activities as well as attending ANZUP Cancer Trials Group Annual Scientific Meeting.

Appointment of Members and Terms of Appointment

The term of appointment is 2 years. Any member of ANZUP is eligible to be a member of subcommittee and is eligible to be a member of more than one subcommittee. Any subcommittee member is eligible to stand for nomination for Chair or Deputy Chair of the subcommittee. Participation is voluntary and expenses will be reimbursed by ANZUP for Subcommittee-related activities.

The role of the subcommittee Chair is to provide leadership and promote participation in the activities of the subcommittee and within ANZUP more broadly. The Chair and Deputy Chair of each subcommittee are appointed by the ANZUP Board on advice from the SAC. The Chair will be a member of the SAC by virtue of the appointment. The Deputy Chair or other SAC member may act as proxy to represent the Chair should the Chair be unable to attend.

The Chair and Deputy Chair appointments will be for a period of three years, with the possibility of an extension for three years. At the end of two terms of appointment, before a member can reapply for a further term in the same position, a significant period must elapse (at least one year). The method of appointment for both the Chair and Deputy Chair positions are specified in the ANZUP cancer Trials Group SOP's (point 1-2; 1-3 respectively).

ANZUP members wishing to join a subcommittee must submit details as follows to the Chair of the subcommittee:

1. Their experience of urogenital cancer/s;
2. Their experience of clinical trial participation (if any);
3. Their involvement with other consumer groups;
4. Their reasons for wishing to join the subcommittee;
5. Whether they are willing to be involved in the promotion of clinical trials research;
6. Their resumé.

TERMS OF REFERENCE FOR SCIENTIFIC ADVISORY COMMITTEE & SUBCOMMITTEES

Essential Criteria

The essential criterion for a member of the Scientific Advisory Subcommittees their commitment to clinical trials as a key strategy for improving the outcomes of those affected by genitourinary cancer. This includes supporting and promoting every person's right to information concerning trials and their right to make a personal, informed choice. Their role is a function within the Scientific Advisory Subcommittee and will be under the direction of the Subcommittee Chair.

Expectations of Members

It is recognised that Subcommittee members will be functioning within the subcommittee on a voluntary basis with professional and family commitments; however, all Subcommittee members are asked to be aware of responsibilities involved regarding their participation in the subcommittee activities and meetings. Members may be given opportunities to participate in National and international meetings including participation in ANZUP Cancer Trials Group presentations. Members will be acknowledged in ANZUP Cancer Trial Group's annual report and associated publications. Availability to attend and/or give presentations at other relevant meetings, forums and conferences is desirable. Members' timely responses to various proposals, protocols and documents will also be sought throughout the year.

All new subcommittee members are also required to sign a Confidentiality Undertaking and are furnished with:

1. ANZUP Cancer Trials Group Scientific Advisory Subcommittee Terms of Reference;
2. Member contact details;
3. Recent Subcommittee meeting minutes;
4. Relevant ANZUP operational and personnel information;
5. Lists of ANZUP Clinical Trials;
6. Any other pertinent information.

Meetings

The disease specific Subcommittee's (Prostate Cancer subcommittee, Renal Cell Cancer Subcommittee, Germ Cell Cancer Subcommittee and Bladder Cancer Subcommittee) should hold a minimum of 2-3 teleconferences a year and at least one face-to-face meeting to review new concepts and generate research proposals as outlined below. These meetings should preferably be held prior to the ANZUP Scientific Advisory Committee meetings in order to be able to have all proposed study concepts approved by subcommittee and submitted for SAC consideration

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Attachment 3: ANZUP Strategic Plan 2010 - 2012



ANZUP STRATEGIC PLAN 2010-2012

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- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies

This will be achieved by:

- Filling a niche in Australia and New Zealand in answering clinical questions that are currently not answered by industry sponsored or other clinical trials.
- Ensuring access to these trials is available as widely as possible for all appropriate Australian and New Zealand patients
- Creating and taking opportunities to support clinical trials in rural and remote areas will be considered and will be the subject of specific fundraising activities.
- Creation of strong links with Cancer Australia and/or other peak bodies aiming to explore and initiate trials in under researched areas.
- Engagement of various professional disciplines at all levels of protocol development and implementation in both clinical and pre clinical research.
- Securing funding to support clinical research training positions.
- Providing opportunities for the next generation of clinical researchers through access to expertise for basic research and clinical trials, including access where appropriate and with ethical approval to data and tissue samples.
- Ensuring processes are in place to ensure high quality data collection and analysis and compliance with Good Clinical Research Practice.
- Identification of strategies for inclusion of functional imaging studies in ANZUP trials
- Promoting systematic collection of tissue and data on trial participants and in general urogenital oncology clinical practice.

- Addressing specific health and medical issues of Culturally and Linguistically Diverse (CaLD) groups and Aboriginal and Torres Strait Islanders (ATSI) by identifying if there is a need to facilitate better clinical and laboratory research in these populations and to develop protocols in such areas.

Strategic Plan:

- Formalise links with key stakeholders and other interested groups, including but not limited to Cancer Australia, NHMRC CTC, COSA, Cancer Voices Australia, PCFA, other Cooperative Trials Groups in Australia and internationally.
- Strategic planning meetings will continue to be held by the Board and the SAC and will be a regular agenda item on meetings of the Board and SAC
- The SAC will identify opportunities for clinical trials in each of the urogenital cancer types, clinical disciplines and types of research, with particular emphasis on the quality and/ relevance of the proposed trials. The SAC will foster concept and protocol development and will prioritise concepts.
- Specific emphasis will be given to maintenance and continuation of existing trials.
- Develop and open a prostate cancer protocol developed through ANZUP systems.
- The Quality of Life and Supportive Care subcommittee and the Translational and Correlative Research subcommittee will consider each concept starting at an early stage of its development, with a view to ensuring that quality and value of each proposal is maximised.
- All appropriate ANZUP protocols will be designed to incorporate systematic tissue collection with annotated outcomes data wherever appropriate. ANZUP will continue to push for coordinated regional and/or state-based tissue repositories, working with other organisations as appropriate.
- The Consumer Advisory Panel will provide input on research priorities, communication strategies, engagement of the community and trial design and conduct.
- The Board will be responsible for logistic development of each trial and securing appropriate funding.
- Links will be formed with other Australian and international cooperative clinical trials groups to enhance opportunities to access other clinical protocols.
- Links will be formed with other Australian and international basic research groups to allow improved access to platform technologies and other expertise in order to add further scientific value to each project.
- Mentorship and training will continue to be key priorities.
- The number and scope of membership of the Consumer Advisory Panel will continue to be enhanced, with input at all stages of protocol development and operations of the SAC and the Board.
- Membership of ANZUP will be increased by:
 - Regular correspondence with members including trial updates, activity, group news, meetings and presentations.
 - Annual Scientific, Strategic Planning and Concept Development Meetings, with attendance strongly encouraged and promoted through the Group's correspondence with members.
 - Targeted liaison with potential new sites with clinical trials capacity, as appropriate.
 - Further development and maintenance of the ANZUP website www.anzup.org
- Appointment of Directors to the Board with financial, commercial, legal and/or fundraising expertise.

Business Plan:

It is recognised that the Cancer Australia Support for Clinical Trials scheme provides necessary support for staff, administration, travel and asset costs. Further expansion of the group, and in particular funding for specific research protocols, will need to be obtained from other sources. This will be a key task for the Board. Specific potential funding sources include:

- Competitive project grants (e.g.: Cancer Australia, NHMRC, Cancer Councils, and International funders)
- Industry support under careful and stringent provisions
- Philanthropic donations (facilitated by active fundraising and by gift recipient tax status). The ANZUP Constitution allows appointment of up to two non-elected Directors; it is envisioned that individuals with fundraising and financial expertise will be targeted for these appointments. The company constitution allows for registration in the States and Territories for the purpose of fundraising.
- Strategic links with community advocacy and fundraising groups (eg Prostate Cancer Foundation Australia).
- Specific consideration will be given to resourcing trials in rural and remote areas.