ANZ GOG

20 years improving life for women through cancer research

2010-2020
PART TWO

OUR PURPOSE

Our purpose is to improve outcomes and quality of life for women with gynaecological cancer through conducting and promoting cooperative clinical trials and undertaking multidisciplinary research into the causes, prevention and treatments of gynaecological cancer.

ACKNOWLEDGEMENT

We acknowledge the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present and all Aboriginal and Torres Strait Islander people, from whatever nation they may come.

In particular, we acknowledge the Gadigal people of the Eora nation, and the people of the Kulin nation as the traditional owners of the lands and waters where our offices are located.

For Māori, the indigenous people of Aotearoa New Zealand we acknowledge Papatuanuku as our Earth Mother, and it is from her bond with Ranginui, the sky father, that we, and all the plants and creatures on earth, descend.

From this whakapapa or lineage, we are connected by a common bond and for us as Māori this translates into an obligation as kaitiaki or guardians to care for and protect our land and resources and to maintain their life-sustaining properties for the benefit of present and future generations.

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> *Our trial portfolio has flourished, as we now have more trials in operation, in development and in the pipeline than ever before. We were also able to establish innovative, world-class research initiatives such as OASIS, TR-ANZGOG, Fund for New Research, and have made exciting plans to launch EDEN, an endometrial cancer research initiative in 2021.*
>
> **ASSOC PROF PHILIP BEALE**

A SHORT HISTORY
OF ANZGOG'S SECOND DECADE

The evolution of ANZGOG during these 10 years has been very substantial, and this is something we should be proud of and should highlight. What ANZGOG has achieved in this time has been an amazing effort, due to an enormous amount of hard work by our members, our Board, by all our collaborators at the NHMRC CTC and made only possible by our ongoing support from Cancer Australia.

In May 2013 we had our strategic planning meeting to map our course over the next 5 years. We sought wide input from many of our members and stakeholders prior to the actual meeting, and 24 Directors and members attended on the day. From that meeting came the following strategic goals:

1. **To undertake a diverse portfolio of clinically important research in gynaecological cancers.**
2. **To develop a national gynaecological cancer biobank.**
3. **To build collaboration with national and international groups with a focus on Asia.**
4. **To be recognised as the leader in gynaecological cancer research in Australia and New Zealand.**
5. **To become a financially sustainable organisation by 2018.**

These strategic goals helped steer the direction of ANZGOG and enabled us to focus on achieving impactful outcomes over those next five years. Our achievements over this time led to significant growth in numbers and in confidence within the ANZGOG Board, staff, and membership, about what ANZGOG can achieve.

Growth in our membership has been a key indicator that we are respected as the peak national organisation in gynaecological cancer research in Australia and New Zealand. In 2010, we had 423 members. By the end of the decade this number had more than doubled to over 1,000.

The progress made in our organisational structure has been a landmark during this decade. Alison Evans, Chief Executive Officer, has been a very big part of this development, allowing us to run like a structured organisation with divisions focusing on operations, trial activity, fundraising and communications. This has made such a huge difference to the solidity of ANZGOG.

We now consult with our Financial Director and Manager – Finance & Business, and the Audit Risk and Compliance Committee, to oversee our finances and risk. This really shows the maturity of our organisation.

Our people are our strength and I want to thank all ANZGOG members, staff and our supporters who have contributed to another successful decade for clinical research in Australia and New Zealand.

Because of their hard-work and determination, we now have more capacity to conduct clinical trials and research, which encourages members to present research ideas to ANZGOG for funding and development. It's great to know an idea is not just a pipe dream.

It is a true honour to be Chair of ANZGOG and to be able to introduce this part-two historical document of our 20-year history.

ASSOC PROF PHILIP BEALE
CHAIR | ANZGOG
AS AT JUNE 2021

ACHIEVING MATURITY AS AN ORGANISATION

INCORPORATED AS A COMPANY LIMITED BY GUARANTEE

Coming into the new decade, ANZGOG had significantly increased its membership, trial portfolio, and international standing as a gynaecological oncology group. The first step as a professional group was becoming incorporated as a company limited by guarantee, which demonstrated the growing maturity of the organisation.

"Becoming a company limited by guarantee signified a coming of age for ANZGOG. Prior to that, we were a small organisation with a small executive and not much process around how we conducted our business.

Although there were questions about whether we could afford to do it, many of us in the executive realised it was really a matter of whether we could afford NOT to do it. Becoming incorporated provided protection for the organisation and for members of the executive and meant that proper governance processes were embedded in the organisation.

Since incorporation, our governance issues are now sorted, affording greater protection for the organisation and allowing us to grow in other areas. This enabled us to develop the ANZGOG profile within the community which we had not been able to previously."

ASSOC PROF ALISON BRAND AM
CHAIR | ANZGOG (2012-2018)
TREASURER | ANZGOG (2002-2009)

ENGAGING MORE MEMBERS IN RESEARCH DEVELOPMENT

ANZGOG's Tumour Working Groups (TWG), established in 2014, were modelled on the Gynecologic Cancer InterGroup (GCIG) approach. The groups were Ovarian, Uterine (and GTD), and Cervix (and Vulva/Vagina). The tumour groups are all chaired by a current member of the Research Advisory Committee and membership comes directly from ANZGOG members. The aim was to encourage new research ideas and proactively look for research opportunities, as well as encourage more people to become directly involved with ANZGOG's work.

It also identified gaps in our trial portfolio and enabled us to concentrate on developing trials for under-represented tumour types.

"Formalising our TWGs aligned ANZGOG to the framework of GCIG and additionally it allowed more people to feel more involved with the work of ANZGOG. The TWGs structure helped spread the workload and provided a mechanism to allow people to work their way up the organisation to positions of higher responsibilities. We knew that if members contributed to the TWGs, then they were committed to our research. This fostered new ideas and new leaders."

"The Tumour Type Working Groups were formed because we recognised that we definitely needed a focus on all gynaecological cancer types. We know that there are sub/rarer tumour types and have become increasingly mindful that our trial portfolio must reflect that. Our mindset has changed over this time to be thinking that we truly can be doing trials in the rare cancer space."

ASSOC PROF PHILIP BEALE
CHAIR | ANZGOG (2018-PRESENT)

ANZGOG TRIALS 2010 - 2020

“ We need to continue to develop better treatments as well as access to preventive measures, so more women in Australia, New Zealand and around the world can live a long and happy life. ”

PROF LINDA MILESHKIN
CHAIR | RESEARCH ADVISORY COMMITTEE (2012-2018)

Prof Linda Mileshkin

CLINICAL TRIALS

OUTBACK

STUDY	OUTBACK
TITLE	A phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone
SUMMARY	The standard treatment for locally advanced cervical cancer is currently radiotherapy combined with chemotherapy (chemo-radiation). Radiotherapy to the pelvis destroys potential cancer cells in the pelvic area and significantly reduces the risk of tumour recurrence in the pelvic area. Giving chemotherapy using a drug called cisplatin during radiotherapy has been shown to increase its effectiveness and is part of standard treatment. Studies among patients with other cancer types have shown that the addition of more chemotherapy after chemo-radiation reduces the risk of tumour recurrence at other places in the body. This has not yet been established for cervical cancer patients. Giving additional chemotherapy after initial standard treatment is known as 'adjuvant chemotherapy'. The objectives of this trial are to find out whether adjuvant chemotherapy (using two other drugs) after chemo-radiation will increase the chances of survival and reduce the risk of tumour recurrence in the pelvis and other places. The risk and severity of side effects and quality of life during and after treatment will also be evaluated and compared. This trial will help the researchers understand the safety and effectiveness of the treatment. In this trial one group will receive standard chemo-radiation alone, whereas the other group will receive standard chemo-radiation and then additional chemotherapy.
ANZGOG PI	Peter MacCallum Cancer Centre
PI INSTITUTION	Prof Linda Mileshkin
CANCER TYPE	Cervical
PHASE	Phase III
TYPE OF TRIAL	Intervention
DRUG/S	Cisplatin, carboplatin, paclitaxel
LEAD GROUP, COUNTRY	ANZGOG-led international trial
COLLABORATIONS	NRG Oncology (GOG & RTOG legacy groups)
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	17 ANZ
RECRUITMENT	926 Total Worldwide, 168 ANZ
FUNDING	NHMRC Project Grant

> *"The OUTBACK results confirm that chemoradiation alone is currently our best standard treatment for women with locally advanced cervical cancer. The addition of adjuvant chemotherapy did not improve 5-year survival rates, but it did add significant side effects. Although some oncologists have been giving adjuvant chemotherapy outside of trials while awaiting the results of OUTBACK, this practice should now stop"*
>
> **PROF LINDA MILESHKIN**

WHAT IS THE FOCUS OF OUTBACK?

OUTBACK is a phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared with chemoradiation alone.

OUTBACK is an international trial led by ANZGOG and the NHMRC Clinical Trials Centre (CTC), ANZGOG's first homegrown study.

The trial has recruited 926 women worldwide, with 168 women recruited in Australia and New Zealand.

In OUTBACK, women are randomised to either standard cisplatin-based chemoradiation or standard cisplatin-based chemoradiation followed by four cycles of adjuvant carboplatin and paclitaxel chemotherapy.

WHY IS OUTBACK IMPORTANT?

OUTBACK originated from an observational study showing that while standard chemoradiation for women with cervical cancer was working well, some women were dying of metastatic disease. The trial aims to show whether addition of adjuvant chemotherapy can improve survival.

The importance of OUTBACK's results were evident as it was chosen to be presented at the 2021 ASCO Annual Meeting Plenary Session, being described by ASCO's President Lori J. Pierce as 'immediately practice-changing'.

> *"OUTBACK has been a fantastic effort from investigators and trial units around the world. This global effort has culminated in a high-quality, rigorously-conducted clinical trial, producing robust results that answer an important question for women with cervical cancer."*
>
> **ASSOCIATE PROF PHILIP BEALE**

WHAT DID OUTBACK FIND?

The trial showed that the addition of adjuvant chemotherapy following chemoradiation did not improve survival compared to standard chemoradiation alone in women with locally advanced cervical cancer.

At 5 years, overall survival was similar in the two treatment groups — 72% among those assigned adjuvant chemotherapy versus 71% among those assigned standard chemoradiation alone. Rates of progression-free survival at 5 years were also similar (63% versus 61%, respectively). Patterns of disease recurrence were also similar in the two treatment groups.

Severe side effects (grades 3-4) within a year of randomisation were experienced by more women assigned adjuvant chemotherapy than standard chemoradiation alone (81% versus 62%).

The trial also found that only 77% of women in each arm successfully completed all components of standard chemoradiation (including external beam radiotherapy, brachytherapy, and concurrent weekly chemotherapy with cisplatin).

> *"OUTBACK was an important homegrown study that has now gone global – something that represents a huge step forward; this was possible because of the excellent structures and people involved – we have to continue to support our own leadership of trials through funding and capacity."*
>
> **DR ALISON DAVIS**

WHAT CAN WE LEARN FROM OUTBACK?

We need to find ways to improve the tolerability and completion of standard chemoradiation, as well as investigate other ways to improve survival rates for this group of women.

CLINICAL TRIALS

PARAGON

STUDY	PARAGON
TITLE	A phase II study of anastrozole in women with potentially hormone sensitive recurrent gynaecological cancers
SUMMARY	The main purpose of this study is to see if anastrozole (an aromatase inhibitor, also known as Arimidex®) which is a hormonal or anti-oestrogen therapy will help reduce the size of tumours and delay the time to progression, as well as improve symptom control and quality of life, in women with potentially hormone responsive recurrent gynaecological cancers. Hormonal therapy is widely used to treat a number of cancers with breast cancer being the most common example. Aromatase inhibitors such as anastrozole are considered the most effective drugs to treat women with hormone responsive breast cancers and are approved for this use. There is evidence that hormonal therapy may also be effective in some women with gynaecological cancers and a variety of different hormonal treatments have been used. Aromatase inhibitors such as anastrozole are a reasonable option in selected patients with recurrent gynaecological cancers because they are generally well tolerated and unlike chemotherapy, can be administered for prolonged periods with fewer side effects and theoretically may also be more effective than other hormonal treatments such a tamoxifen.
ANZGOG PI	Prof Michael Friedlander AM
PI INSTITUTION	Prince of Wales Hospital
CANCER TYPE	Ovarian, endometrial
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Anastrozole
LEAD GROUP, COUNTRY	ANZGOG-led international trial
COLLABORATIONS	Cancer Research UK Clinical Trials Unit (CRCTU) and UZ Leuven
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	23 ANZ
RECRUITMENT	333 Total Worldwide, 219 ANZ
FUNDING	Cancer Australia, OCRF

> *"PARAGON was a trial with a design that was ahead of its time when I proposed the study in 2008. I was interested in running clinical trials in rare cancers but there were many barriers to doing so. Not least of these were the reluctance of investigators to consider opening trials in their centres due to the time, effort and associated costs when they knew they were only likely to recruit a few patients. I thought we could overcome this major barrier using a basket design. Although I didn't call it that at the time, in essence this is what PARAGON was."*
>
> **PROF MICHAEL FRIEDLANDER AM**

WHAT IS THE FOCUS OF PARAGON?

PARAGON was an investigator-initiated trial led by ANZGOG carried out in collaboration with colleagues in the United Kingdom and Belgium.

The trial included seven separate phase 2 trials embedded in a single protocol.

PARAGON recruited almost 350 women. All women had recurrent gynaecological cancers and shared one common feature: their cancers were oestrogen receptor (ER) and/ or progesterone receptor (PR) positive and may therefore potentially respond to anti-oestrogens.

WHAT WAS NEW ABOUT PARAGON?

PARAGON was the first prospective trial of hormonal therapy (anastrozole) in women with rare gynaecological cancers.

PARAGON demonstrated that it is possible to carry out trials in patients with uncommon/ rare gynaecological cancers. The basket design meant a single submission to an ethics committee and the potential to recruit many more patients to the study, which made it very attractive to centres.

PARAGON included the following subsets:

1. Asymptomatic patients with a rising CA125 following first line chemotherapy
2. Patients with platinum-resistant ovarian cancer in whom chemotherapy was not indicated
3. Patients with recurrent low-grade serous ovarian cancers
4. Patients with recurrent endometrial cancer
5. Patients with recurrent granulosa cell tumours
6. Patients with recurrent endometrial stromal sarcomas
7. Patients with uterine leiomyosarcomas and other rare gynaecological sarcomas.

WHAT DID PARAGON FIND?

A key finding was that the objective response rates in cancers such as endometrial stromal sarcomas and granulosa cell tumours were much lower than suggested by the literature (which at the time was made up of retrospective case series and case reports).

PARAGON was also the first prospective trial of hormonal therapy in low-grade serous cancer and confirmed the results of retrospective case series.

Results have been published in leading international journals. [1,2,3,4,5,6]

> *"A key lesson was that we should have mandated the provision of a tumour block from initial surgery as a requirement for eligibility to the study. It is very difficult to obtain tumour tissue after patients have been treated and this has impeded the important translational research component. This has been a formidable barrier to overcome but I am committed to seeing it through."*

WHAT IMPACT HAS PARAGON HAD?

PARAGON has answered a number of important questions regarding the potential role of aromatase inhibitors in ER/PR-positive gynaecological cancers.

Although the expression of these receptors is often high in many gynaecological cancers, the response rates are significantly lower than in breast cancer, which raises questions about mechanisms of resistance and importantly whether they can be overcome.

There have been major and transformative changes to the management of women with hormone receptor positive metastatic breast cancer in recent years. We now have a greater understanding of resistance mechanisms. Drugs such as CDK4/6 inhibitors and PIK3CA inhibitors are now available in combination with hormonal therapy to circumvent resistance.

NEXT STEPS

Given the success of PARAGON we have applied for a grant to carry out PARAGON 2, which builds on the foundations of PARAGON and incorporates agents that are used in ER-positive metastatic breast cancer. PARAGON 2 will be led by Assoc Prof Chee Lee. PARAGON cemented the importance of ANZGOG in being at the forefront of innovative trial designs to broaden the access of patients with rare cancers to participate in clinical trials. This will continue if PARAGON 2 is successful in the recent grant submission.

"The most important learning for me personally was that trials such as PARAGON can only be carried out with international collaboration. The experience has demonstrated the importance of working with a committed team to achieve success."

PROF MICHAEL FRIEDLANDER AM

[1]Bonaventura A, O'Connell RL, Mapagu C et al. Paragon (ANZGOG-0903): phase 2 study of anastrozole in women with estrogen- or progesterone-receptor–positive platinum resistant or refractory recurrent ovarian cancer. Int J Gynecol Cancer 2017;27(5):900-906.
[2]Kok P-S, Beale P, O'Connell R et al. Paragon (ANZGOG-0903): A phase 2 study of anastrozole in asymptomatic patients with estrogen and progesterone receptor-positive recurrent ovarian cancer and CA125 progression. J Gynecol Oncol. 2019;30(5):e86
[3]Mileshkin L, Edmondson R, O'Connell RL et al. Phase 2 study of anastrozole in women with recurrent estrogen (ER)/progesterone (PR) positive endometrial cancer: The PARAGON trial – ANZGOG 0903. Gynecol Oncol 2019;pii: S0090-8258(19)31232-6. doi: 10.1016/j.ygyno.2019.05.007. (Epub ahead of print)
[4]Tang M, O'Connell RL, Amant F et al. PARAGON: A Phase II study of anastrozole in patients with estrogen receptor-positive recurrent/metastatic low-grade ovarian cancers and serous borderline ovarian tumors. Gynecol Oncol 2019;154(3):531-538
[5]Sjoquist KM, Martyn J, Edmondson RJ et al. The Role of Hormonal Therapy in Gynecological Cancers - Current Status and Future Directions. Int J Gynecol Cancer 2011;21(7):1328-33
[6]Sommeijer DW, Sjoquist KM, Friedlander M. Hormonal treatment in recurrent and metastatic gynaecological cancers: a review of the current literature. Curr Oncol Rep 2013;15(6):541-8.

Prof Michael Friedlander AM

"Financial sustainability was a real goal of mine as Chair, and I think we really achieved that in the last decade. The establishment of the Fund for New Research and the OASIS initiative means we now have a mechanism in place to fund projects that are presented to us from members."

ASSOC PROF ALISON BRAND AM
CHAIR | ANZGOG (2012-2018)
TREASURER | ANZGOG (2002-2009)

BUILDING FINANCIAL STABILITY

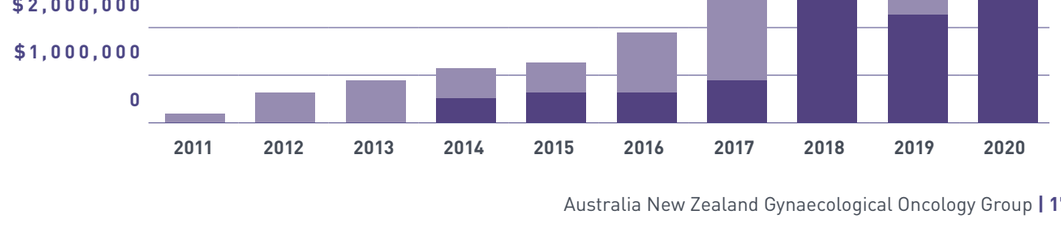
"One of our biggest achievements over this decade was our government grant success. Between the years of 2012-2015, we were successful in every single grant that we submitted to government funding agencies. This really demonstrated the quality of our research, as these government grants are incredibly competitive, with only around 14% of applications usually being successful."

ASSOC PROF ALISON BRAND AM
CHAIR | ANZGOG (2012-2018)
TREASURER | ANZGOG (2002-2009)

"We have done fine work in establishing our financial credentials. We now have a much safer footing (in the last 5 years in particular) with our financial stability. Both Alison Evans and Assoc Prof Alison Brand AM have been instrumental in this. They both had a view that we had to go from being a part-time amateur group to a full-time professional organisation with clear, 2–5-year strategic goals and alignment."

ASSOC PROF PHILIP BEALE
CHAIR | ANZGOG (2018-PRESENT)

REVENUE AND NET SURPLUS/ (DEFICIT) FROM OPERATIONS



TOTAL EQUITY INCLUDING PROJECT RESERVES

CLINICAL TRIALS

ANZGOG 1103

STUDY	ANZGOG 1103
TITLE	Phase I/II BNC105P combination study in partially platinum sensitive ovarian cancer patients in first or second relapse
SUMMARY	The purpose of this study is to determine if a new drug, BNC105P, is a safe and active treatment for people with advanced ovarian cancer that has progressed after treatment with standard chemotherapy. BNC105P is a new experimental drug that has been tested in 60+ people with a variety of cancers including ovarian cancer, and has not been registered or approved for use outside of research studies in Australia, New Zealand, the USA or any other country.
ANZGOG PI	Prof Danny Rischin
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
TYPE OF TRIAL	Intervention
LEAD GROUP, COUNTRY	ANZGOG-led international trial
COLLABORATIONS	Hoosier Cancer Research Network (HCRN)
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	4 ANZ
RECRUITMENT	15 Total Worldwide, 12 ANZ
FUNDING	Bionomics

COLLABORATIONS
WITH LOCAL OPERATING CENTRES

ANZGOG have developed local collaborations with Australian-based clinical trial operating centres and have forged a longstanding relationship with the NHMRC Clinical Trials Centre, at the University of Sydney. ANZGOG also have collaborations with other operating centres such as BaCT at Peter MacCallum Cancer Centre, the Queensland Centre for Gynaecological Cancer Research at the University of Queensland, and others to foster new trials and contribute to their development.

Strong local collaborations are fostered with institutions such as Sydney and Melbourne Universities, the Walter & Eliza Hall Institute, QIMR Berghofer Medical Research Institute, Queensland University of Technology, and the University of Western Australia, which ensures a diverse approach to the development of both research ideas and clinical trials.

NHMRC Clinical Trials Centre

THE UNIVERSITY OF SYDNEY

OvQuest

STUDY	OvQuest
TITLE	Life after the diagnosis and treatment of ovarian cancer – An international survey of symptoms and concerns in ovarian cancer survivors
SUMMARY	We know that after finishing treatment for ovarian cancer, most people have a number of unique health needs. In the short term, they are often troubled by side-effects of their treatment and worried about the risk of their cancer coming back. For some women, side-effects may persist or new health problems might arise in the longer term. We also know that many women experience psychological and practical problems after cancer that can affect their quality of life. OvQuest is an international, internet-based, cross-sectional questionnaire which explored symptom burden and quality of life (QOL) after treatment for ovarian cancer.
ANZGOG PI	Dr Kate Webber
PI INSTITUTION	Prince of Wales Hospital and Monash University
CANCER TYPE	Ovarian
LEAD GROUP, COUNTRY	ANZGOG and Ovarian Cancer Australia-led international study
COLLABORATIONS	Ovarian Cancer Consumer Groups in the USA, United Kingdom, Canada and Germany (NOGGO)
RECRUITMENT	1360 Total Worldwide, 208 ANZ

Prof Peter Sykes
Chair | ASM Steering Committee (2014 - 2017)

ANNUAL SCIENTIFIC MEETINGS (ASM)

Providing education and opportunities for information exchange for our members is a key element within ANZGOG's strategic goals. The ANZGOG ASM enables attendees to learn about the latest developments in gynaecological cancer and provides education and capacity building opportunities amongst members and industry personnel. Each year we develop a program of keynote speakers and information on gynaecological cancer treatments, clinical trials and other clinical work from Australia, New Zealand and around the world.

ANZGOG's ASM brings together national and international experts in gynaecological medicine, radiation and surgical oncology, pathology, basic scientists, translational and quality of life researchers, study coordinators and nurses, as well as our partners in the pharmaceutical industry.

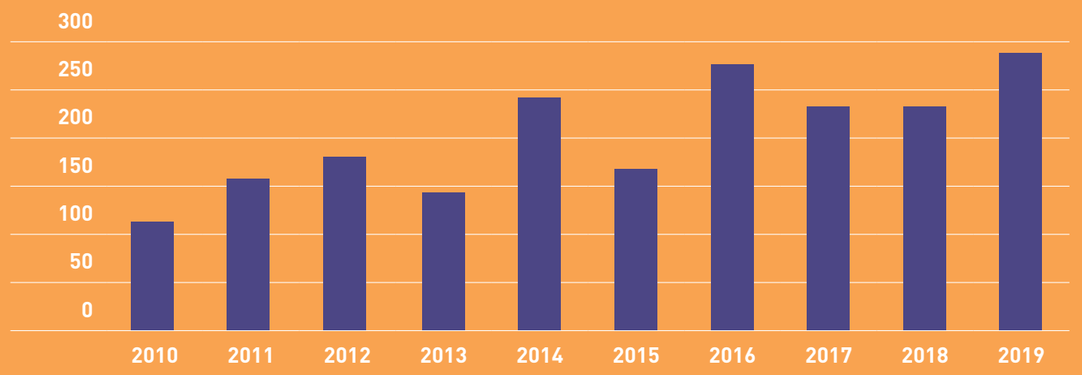
The meeting has been hosted in numerous Australian locations so far, including Noosa, Melbourne, Gold Coast, Sydney, Canberra and Brisbane. Since 2010, ANZGOG's ASM attendance has more than doubled, displaying the increasing interest within our growing membership:

CONNECTING PURE SCIENTISTS AND CLINICIANS

The 2015 ASM had a celebratory atmosphere, as ANZGOG marked its 15th anniversary of conducting research, yet there was also another significant milestone that took place – the inaugural Pure Science Symposium (PSS). Held as part of the conference, the PSS was a way of matching pure scientists with clinical researchers, a premise that was ahead of its time.

> *"The Pure Science Symposium was a brainchild of Peter Sykes, and a truly inspired decision (it actually came out of the blue!). We know that scientists in the lab are sources of much of the data that leads to clinical trial development, but prior to the PSS there was a disconnect between the scientists and clinicians. The PSS has been a way to bring them together and it has been a hugely successful, mutually beneficial relationship."*
>
> **ASSOC PROF ALISON BRAND AM**
> **CHAIR | ANZGOG (2012-2018)**

ASM ATTENDEES



The 2020 ASM was cancelled due to the COVID-19 pandemic

CLINICAL TRIALS

MOST-OPAL

STUDY	MOST-OPAL
LONG TITLE	A prospective study to evaluate the utility of the MOST questionnaire to detect symptoms of recurrence and document the concerns and adverse effects reported by patients after completing first line treatment with surgery and chemotherapy – a sub-study of the OPAL trial
LAY SUMMARY	The purpose of this study is to improve the detection of symptoms of recurrence and the documentation of the late effects of 1st line treatment in patients with advanced ovarian cancer through a structured follow up using the MOST questionnaire and to compare this with standard clinical follow up.
ANZGOG PI	Prof Michael Friedlander AM and Prof Penelope Webb
PI INSTITUTION	Prince of Wales Hospital and QIMR Berghofer Medical Research Institute
CANCER TYPE	Ovarian
LEAD GROUP, COUNTRY	ANZGOG and QIMR Berghofer Medical Research Institute-led national study
SPONSOR	BUPA
OPERATING CENTRE	QIMR Berghofer Medical Research Institute
NUMBER OF SITES	19 ANZ (OPAL Sites)
RECRUITMENT	812 ANZ
FUNDING	BUPA Health Foundation Grant & QIMR Berghofer Weekend to End Women's Cancers 2014

"The success of this study was due to the spirit of collaboration that exists in Australia and the close working relationships ANZGOG has with leading scientists and researchers throughout the country. The major learning is that we need to continue to foster and strengthen these relationships as they cannot be taken for granted. The study also demonstrates the importance of scientific exchange at the ANZGOG ASMs, as many successful studies such as this have directly emerged out of discussions held at the meeting."

PROF MICHAEL FRIEDLANDER AM

WHAT IS THE FOCUS OF MOST-OPAL?

The MOST-OPAL study was an unexpected extension of the Symptom Benefit Study (SBS) and development of the Measure of Ovarian Cancer Symptoms and Treatment Concerns (MOST). This was an ANZGOG-led sub-study embedded into the OPAL study led by Prof Penny Webb.

An international online survey of more than 1000 survivors of ovarian cancer drew attention to the high symptom burden reported by many patients after completing chemotherapy. This highlighted the need to give more attention to patients after completing chemotherapy and identify those with problems amenable to early intervention.

The aims of the MOST-OPAL study were to document the frequency, severity and trajectory of self-reported symptoms and adverse effects of treatment following first-line chemotherapy, and to investigate the utility of MOST to detect symptoms of recurrence.

From 6 months after diagnosis (coinciding with the completion of chemotherapy), OPAL participants completed the MOST questionnaire every 3 months up to a maximum of 3.5 years (maximum 15 MOST questionnaires).

"I presented the concept for MOST-Follow at ANZGOG's 2012 ASM. This led to discussions with Penny Webb who agreed to include the study as part of OPAL follow up. This was critical to its success as it would have been almost impossible to get sufficient funding to carry out this study independently of OPAL. We secured funding from BUPA which allowed the study to be carried out."

The OPAL trial is following up a national cohort of women newly diagnosed with ovarian cancer and attempting to identify whether potentially modifiable lifestyle choices including physical activity, diet and medication use are associated with recurrence and survival.

WHAT DID MOST-OPAL FIND?

At 30 April 2018, 452 of 742 (61%) OPAL participants who completed first-line chemotherapy had experienced a recurrence of their disease, with a median time to recurrence of 11.7 months (range 2–55 months) after completion of therapy. An important finding was that the MOST abdominal symptom score increased 2–3 months before recurrence was diagnosed / start of chemotherapy for recurrence.

The majority of women in the MOST-OPAL study reported high levels of side-effects and other concerns while on treatment, with over half of participants still reporting moderate to severe symptoms of peripheral neuropathy such as 'pins and needles' and 'sore hands and feet' two years after completing treatment and 50–60% still experienced moderate to high levels of fatigue and sleep problems. Of note, emotional wellbeing was persistently low in over 40% of participants at 12–18 months following completion of first-line treatment. Patients with baseline MOST scores of ≥35 were more likely to have moderate to severe symptoms two years after completing treatment.

NEXT STEPS

The findings of MOST-OPAL have directly led to a randomised trial: *Getting the MOST out of follow-up: a randomised controlled trial to compare three-monthly nurse-led telephone follow-up, including monitoring serum CA125 and patient reported outcomes using the MOST (Measure of Ovarian Symptoms and Treatment concerns) with routine clinic-based follow-up, following completion of first-line chemotherapy in patients with epithelial ovarian cancer.*

The trial is being led by Dr Paul Cohen and the pilot study is funded by ANZGOG's Fund for New Research Program, the Western Australian Health Translation Network, and the Australian Government's Medical Research Future Fund (MRFF) as part of the Rapid Applied Research Translation program. The study's aim is to assess the health-related quality of life of women undergoing this novel mode of follow-up compared to conventional hospital clinic-based follow-up plus completion of the MOST. This study will also inform the design of a larger phase 3 randomised controlled trial.

Dr Pearly Khaw
Radiation Oncologist
ANZGOG Director (2017-present)

RADIATION ONCOLOGY WORKSHOPS

The Radiation Oncology Workshops were developed to become an opportunity for radiation oncologists at ANZGOG's ASMs with a special interest in the management of gynaecological malignancies to discuss clinical conundrums, new concepts, published guidelines and adapt these to suit the Australian and New Zealand workspace.

Initially, they were utilised to encourage interest and involvement by radiation oncologists who otherwise would not have heard of ANZGOG and their important role in clinical trials in our niche space. Later, it also provided an opportunity for both gynae-oncologists and medical oncologists to participate in the workshop and increase their understanding of the field of Radiation Oncology.

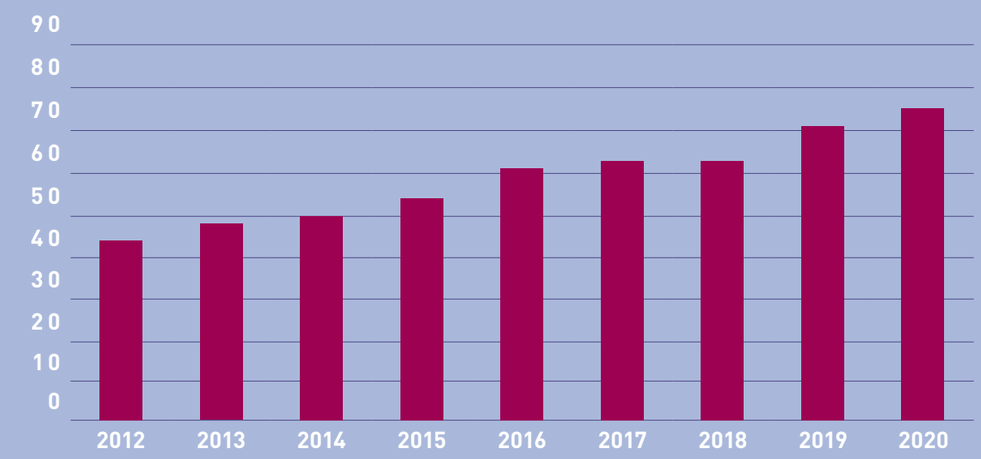
The workshops have covered a number of different formats over the years, but their popularity has meant that ANZGOG have been able to invite a number of key radiation oncologists to the ASMs, including Akila Vishwanathan, Remi Nout, Anuja Jhingran, Michael Milosevic, and Wui Jin Koh, all of whom hold and have held prominent positions within the Radiation Oncology community.

Key factors around the use of radiation therapy were discussed, including brachytherapy, in challenging situations, as well as the guidelines for radiotherapy contouring and those defining the rationale and inclusion of radiation in the management of each of the tumour types. Overall, these workshops have not only provided an educational opportunity but also one of increased collaboration with the other specialty groups involved in the management of gynaecological cancer.

"The topics discussed at the Radiation Oncology Workshops have often proven to be of interest to our surgical colleagues and with their insightful and challenging comments, have made for a lively discussion within the workshops. These discussions have then developed and enhanced the mutual respect and understanding between the two groups within ANZGOG."

DR PEARLY KHAW
RADIATION ONCOLOGIST
ANZGOG DIRECTOR (2017-PRESENT)

RADIATION ONCOLOGISTS IN ANZGOG'S MEMBERSHIP



CLINICAL TRIALS

ICON8

STUDY	ICON8
TITLE	An international phase III randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer
SUMMARY	Ovarian cancer is usually treated by a combination of surgery and chemotherapy. The chemotherapy used for ovarian cancer is usually two drugs, carboplatin and paclitaxel (also sometimes called Taxol). These drugs are internationally recommended by experts for the treatment of ovarian cancer. They are referred to as 'standard chemotherapy' and they are approved for use in Australia for the treatment of ovarian cancer. This treatment is usually given six times, once every three weeks over 18 weeks (also known as six cycles). Although in many patients surgery is performed before chemotherapy starts, research has shown that in some cases it is safe to delay surgery until 3 cycles of chemotherapy have been given. Recent studies have suggested that giving chemotherapy more frequently than once every three weeks is also effective but may also incur more side effects. This type of treatment, known as dose-fractionated chemotherapy involves giving paclitaxel or carboplatin at a lower dose every week during treatment so that a smaller dose of chemotherapy is given every week for 18 weeks rather than a larger dose once every three weeks. In this study we want to find out if weekly chemotherapy is more effective than standard (3 weekly) chemotherapy in treating ovarian cancer. We also want to see if weekly chemotherapy causes more or fewer side-effects than standard chemotherapy. Although weekly chemotherapy involves more doses of chemotherapy than standard chemotherapy, the treatment course is the same length for both. Although the drugs are given at different doses and schedules, all patients will receive a very similar total dose of both drugs over the 18 week treatment.
ANZGOG PI	Dr Andrew Dean
PI INSTITUTION	St John of God Hospital, Subiaco
CANCER TYPE	Ovarian
PHASE	Phase III
TYPE OF TRIAL	Intervention
DRUG/S	Carboplatin, paclitaxel
LEAD GROUP, COUNTRY	Medical Research Council (MRC)/University College London (UCL)-led international trial; ANZGOG-led in Australia and New Zealand
COLLABORATIONS	Cancer Trials Ireland (ICORG), Grupo de Invesitgación en Cáncer de Ovario y Tumores Ginecológicos de México (GICOM), Korean Gynecological Oncology Group (KGOG)
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	19 ANZ
RECRUITMENT	1,566 Total Worldwide, 70 ANZ
FUNDING	Cancer Australia

CLINICAL TRIALS

REZOLVE

STUDY	REZOLVE
TITLE	A phase II study to evaluate the safety and potential palliative benefit of intraperitoneal bevacizumab in patients with symptomatic ascites due to advanced chemotherapy resistant ovarian cancer
SUMMARY	The purpose of this study is to investigate whether a short infusion (injection) of a drug called bevacizumab into the abdominal cavity (known as intraperitoneal infusion) after drainage of excess fluid in the abdomen (called 'ascites') may delay the return of the ascites. Other researchers have shown that an infusion of bevacizumab into the abdominal cavity has been effective in delaying the time it has taken for ascites to return. We would like to investigate this further in this clinical trial to see whether an intraperitoneal infusion of bevacizumab is effective and safe. Bevacizumab is available for use in Australia where it is approved to treat some patients with colorectal, breast, lung, kidney and brain cancers. It is also approved for the treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer where it may be given in combination with carboplatin and paclitaxel as chemotherapy for newly diagnosed patients. Bevacizumab is not being administered as chemotherapy in this study.
ANZGOG PI	Prof Michael Friedlander and Dr Katrin Sjoquist
PI INSTITUTION	Prince of Wales Hospital and St George Hospital
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Bevacizumab
LEAD GROUP, COUNTRY	ANZGOG-led in Australia and New Zealand
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	5 ANZ
RECRUITMENT	24 ANZ
FUNDING	OCRF, Cancer Australia

CRP Members (L-R) Cheryl Waller, Rhonda Beach and Wanda Lawson at an ANZGOG ASM at the ANZGOG 2016 ASM

EMBEDDING CONSUMERS IN OUR RESEARCH

Consumers have played a critical role in ANZGOG's research review process for several years, thanks to the inspiring and enthusiastic ambassadors who form the Consumer Research Panel (CRP).

ANZGOG believes that those who are affected by the research, should have a say in what is researched and how that research is conducted. This principle is what led to the establishment of the Consumer and Community Committee (CCC) in 2008, which eventually evolved into the CRP.

"*ANZGOG's Consumer Research Panel is the mechanism for advice and input from gynaecological cancer survivors and their carers. Internally we work closely with the ANZGOG researchers on the Tumour Working Groups, EDEN and OASIS Initiatives, as well as the Research Advisory Committee by providing our patient perspective and insight into trial development. Externally we share our knowledge through education, media representation and public speaking. We are provided with multiple opportunities to connect with clinicians, researchers and consumers in meaningful ways.*

ANZGOG is likely to have engagement with or involvement by more than 300 consumers annually. From them, we know that what is wanted is to find new ways to improve treatments and the quality of life for people with disease. Clinical trials are the best way to provide these outcomes for gynaecological cancer patients and are a critical way to advance the science of gynaecological cancer. As CRP panel members we are involved in determining our own future.

Consumer Research Panel members have many opportunities to influence research direction within ANZGOG. At a grass roots level - through membership of our Tumour Working groups, where early-stage concepts are discussed, research gaps identified, and priorities discussed. We also review clinical trial concepts submitted to the Research Advisory Committee, provide feedback to researchers on the content included in Patient Information and Consent forms (PICFS), are Associate Investigators on grant submissions, and assist the development of trial protocols. Many of our team members have also participated in a clinical trial themselves - ensuring that we have touch points at all levels of the research process.

In the 10 years I have been involved with the CRP – I have seen many opportunities for consolidating the consumer voice. Major changes in the CRP over those years have been to tighten our focus into a group with research priorities at front and centre, who can stand shoulder to shoulder with researchers. We are now involved at both strategic and operational levels. Our activities allow us to not only influence research direction, but to identify gaps, participate in research design – and provide consumer feedback. The CRP see the way of the future as patient driven science and technology."

MS WANDA LAWSON
CHAIR | CONSUMER RESEARCH PANEL
(2017-PRESENT)

CLINICAL TRIALS

OVAR 2.21

STUDY	OVAR 2.21
TITLE	A prospective randomised phase III trial of carboplatin/gemcitabine/bevacizumab vs. carboplatin/pegylated liposomal doxorubicin/bevacizumab in patients with platinum-sensitive recurrent ovarian cancer
SUMMARY	The aim of this research study is to compare the following chemotherapy regimens in order to find out which combination is more effective in preventing or delaying the spread of ovarian cancer, and which is better tolerated by patients. The two chemotherapy regimens are bevacizumab, gemcitabine and carboplatin; and bevacizumab, carboplatin and pegylated liposomal doxorubicin (PLD). Both chemotherapy regimens will be followed by maintenance treatment with bevacizumab. Carboplatin, gemcitabine and PLD are commonly used standard treatments for ovarian cancer and each has a defined mechanism of action. Bevacizumab is a targeted anti-cancer drug that works by disrupting the blood supply to the cancer to stop or slow its growth. Bevacizumab is approved in Australia to treat recurrent ovarian cancer when used in combination with carboplatin and gemcitabine. However, it is not approved for use in combination with carboplatin and PLD.
ANZGOG PI	Dr Catherine Shannon
PI INSTITUTION	Mater Cancer Care Centre
CANCER TYPE	Ovarian
TYPE OF TRIAL	Intervention
DRUG/S	Bevacizumab, carboplatin, gemcitabine, pegylated liposomal doxorubicin
LEAD GROUP, COUNTRY	GCIG Intergroup Trial: Arbeitsgemeinschaft Gynackologisehe Onkologie (AGO)-led international trial; ANZGOG-led in Australia and New Zealand
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	21 ANZ
RECRUITMENT	682 Total Worldwide, 76 ANZ
FUNDING	AGO

"It's the breadth of the areas of research, with expansion into all the major disease subtypes (ovarian, endometrial, cervical) as well as rare subtypes and Quality of Life studies, that's our strength."

DR ALISON DAVIS
CHAIR | RESEARCH ADVISORY COMMITTEE
(2018 – PRESENT)

Dr Alison Davis

CLINICAL TRIALS

ECHO

STUDY	ECHO
TITLE	A phase III randomised, controlled trial of exercise during chemotherapy for patients commencing first line treatment of ovarian cancer
SUMMARY	Benefits from exercise may be accrued through improved physical well-being, reduced treatment-related side effects, better treatment adherence, better overall quality of life, lower associated health care costs, and perhaps even longer survival. However, there is a lack of evidence and no randomised trials of exercise interventions in ovarian cancer. Observational studies are insufficient to determine cause and effect; randomised trials are needed to provide level one evidence and change clinical practice. This trial will identify whether incorporation of an exercise program into the current standard of care for women undergoing chemotherapy for primary ovarian cancer is a clinically effective and cost-effective way to improve health outcomes in this patient group. Importantly, should it prove cost-effective, translating findings into practice is feasible, since we already have a work-force trained in exercise prescription for special populations (AEPs) and a national funding system that supports the delivery of exercise as a form of treatment (through the Medicare-funded Chronic Disease Care Plan). Findings from this work will address gaps in the literature currently preventing the translation of exercise into standard cancer care.
ANZGOG PI	Prof Sandi Hayes
PI INSTITUTION	Griffith University
CANCER TYPE	Ovarian Cancer
PHASE	Phase III
TYPE OF TRIAL	Intervention
COLLABORATIONS	Griffith University and ANZGOG-led national trial
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	11 ANZ
TARGET RECRUITMENT	500 ANZ
FUNDING	Cancer Australia/Cancer Council Australia Recruitment support from World Cancer Research Fund (WCRF) Cancer Australia Project Grant Cancer Council Queensland Accelerating Collaborative Research Program

> *"While we're unclear whether exercise during treatment for ovarian cancer will lead to benefits in quality of life or survival, there is good evidence to suggest that participation in the trial is associated with very low risk of adverse effects or events."*
>
> **PROF SANDI HAYES**

WHAT IS THE FOCUS OF ECHO?

ECHO is a phase 3, randomised, controlled trial evaluating the effect of an exercise intervention among women undergoing chemotherapy for ovarian cancer.

The aim of the study is to evaluate the effects of an exercise intervention during first-line chemotherapy for ovarian cancer on physical wellbeing, chemotherapy-related adverse events and adherence, physical function, overall QoL, progression-free survival and health care resource use.

This trial, led by Griffith University and ANZGOG, will recruit 500 patients across Australia and New Zealand. The trial population represent a homogenous group of women with different types of ovarian cancer.

WHAT IMPACT COULD ECHO HAVE?

There has been a shift over time in perceptions of the value of exercise in cancer control. While the majority of clinicians would agree that exercise likely has benefits, there is still insufficient conviction to truly integrate exercise as part of routine cancer care. It is also a reality that if every clinician were to recommend exercise, there would be insufficient resources available to support referral, with the risk of inequity in its uptake.

ECHO will identify whether incorporation of an exercise program into the management of ovarian cancer is an effective and cost-effective way to improve health outcomes in this patient group.

ECHO is one of only four ongoing trials worldwide that are specifically designed to address gaps in evidence about the benefits of exercise in people with cancer. To the best of our knowledge, this is the only exercise trial of women with ovarian cancer during chemotherapy worldwide, with results able to address gaps in the literature currently preventing the translation of exercise into standard cancer care.

Once completed, we will know to what extent women may benefit from exercise following diagnosis with ovarian cancer, and what exercise treatment should look like (that is, what women should do, how and when).

Women in the intervention group in ECHO receive a supervised exercise program (total weekly dose: 150 minutes of moderate-intensity, aerobic- and resistance-based exercise) throughout the duration of their chemotherapy (~18 weeks).

> *"Administration of an exercise intervention trial requires a different approach and different expertise to drug or surgical trials. ANZGOG, and particularly Alison Evans, were keen to make this work and I have felt very supported by them."*

WHAT LESSONS CAN ANZGOG LEARN FROM ECHO?

ECHO is a unique trial for ANZGOG – due to the type and nature of the treatment being evaluated it is unlike more traditional ANZGOG drug and surgical trials. Australia is still building its skills and understanding in the administration of exercise oncology trials and ECHO will provide us with important learnings.

As an example, managing the process of patient recruitment centrally, but also separately to the central administration of data collection and intervention delivery for a trial such as ECHO can be challenging. Educating site staff involved with recruitment, consenting and randomisation around who is responsible for what aspects of the trial is more complex than a traditional drug trial, and vitally important for the smooth running of the trial.

Importantly, ECHO adheres to the same strict clinical trial guidelines used in drug and surgical trials. This rigour will ensure that findings have the potential to influence clinical practice first and foremost for Australian women and potentially for women worldwide.

NEXT STEPS

The benefits of exercise in driving improved cancer outcomes are not limited to ovarian cancer. There is definitely scope in endometrial cancer to explore the role and value of exercise. Such a study would need to focus on improving quality of life and prevention of future disease.

Assoc Prof David Tan
Chairman of Asia-Pacific Gynaecologic Oncology Trials (APGOT)

LOCAL & GLOBAL COLLABORATIONS

ANZGOG has continued to strengthen its local and global connections year on year, fostering multidisciplinary collaboration that ensures the relevance, vibrancy, and impact of our research agenda.

LOCAL COLLABORATIONS

ANZGOG collaborates with many universities, research institutes and hospitals in Australia and New Zealand. Our clinical trials are conducted with a number of operating centres including the NHMRC Clinical Trials Centre and Centre for Biostatistics and Clinical Trials (BaCT).

Many ANZGOG trials are conducted cooperatively with other clinical trials groups such as Psycho-oncology Cooperative group (PoCoG), Urogenital and Prostate Group (ANZUP), Breast Cancer Trials, and Gastrointestinal Trials Group (AGITG). ANZGOG also works closely with the Quality of Life Office, CREST Health Economics and the Genomic Cancer Clinical Trials Initiative to foster new trials and contribute to their development.

INTERNATIONAL COLLABORATIONS

ANZGOG's international collaborations are fostered through its individual members and organisational membership of the Gynecologic Cancer InterGroup (GCIG) with 32 member countries. ANZGOG has been a member of the GCIG since 2002. This unique collaboration with other international cooperative clinical trials groups through the GCIG has allowed ANZGOG to be involved in significant international research trials and to provide important leadership in advancing international gynaecological cancer research.

ANZGOG has become a leading participant in the GCIG, with members continuing to hold a number of leadership positions within the group, demonstrating ANZGOG's position as a world leader in gynaecological cancer.

WORKING WITH ASIA

ANZGOG has developed a range of links with Asia through the GCIG. The Asia Pacific Gynaecologic Oncology Trials Group (APGOT) was formed to focus on collaborative studies in gynaecological cancer within the Asia Pacific region, strengthening capabilities and ensuring a greater range of trials available for women. As one of the inaugural members, ANZGOG participated in the formation of the Asia Pacific Gynecological Oncology Trials group (APGOT) in November 2019.

APGOT focuses on Phase II Clinical Trials and studies that can be co-developed with industry funders. ANZGOG has collaborated on two studies with Singapore as part of the OASIS Research Initiative (VIP and MOCCA).

SECTORS UNITING FOR CHANGE

ANZGOG joined with Ovarian Cancer Australia (OCA) and the Australian Society of Gynaecologic Oncologists (ASGO) to launch the Ovarian Cancer National Action Plan (NAP) 2020 – 2025.

The NAP sets out a roadmap for tackling ovarian cancer. It was developed over many months in partnership with key organisations, women living with ovarian cancer and opinion leaders who play an instrumental role in research, treatment and support aimed at improving survival rates and quality of life and reducing the incidence of ovarian cancer in Australia. ANZGOG, as the only national gynaecological cancer research group, considered it important to support the input to this plan.

> *"Global collaborations are the key to our success. ANZGOG members continue to participate in the Gynecologic Cancer InterGroup, with several members appointed as Chairs or Co-chairs of various GCIG committees."*

ASSOC PROF PHILIP BEALE
CHAIR | ANZGOG (2018-PRESENT)

CLINICAL TRIALS

PHAEDRA

STUDY	PHAEDRA
TITLE	A phase II trial of durvalumab in advanced endometrial cancer
SUMMARY	The purpose of this study is to look at the effectiveness of durvalumab in two specific types of advanced or secondary endometrial cancer. These two groups are based on a particular type of endometrial cancer pattern, known as mismatch repair. This relates to the way the cells of the body, including cancer cells, grow and make new cells. In this normal growing process, cells are checked for errors or mistakes and if possible are repaired before a new cell is made. This is so that a perfect copy of the cell can be made. We call this process of checking and repairing cells "mismatch repair". As we get older, or in some familial cancer conditions; this checking and repair process is faulty. The group of cancers that have faulty "check and repair" processes are called "mismatch repair deficient". The group of cancers that have working "check and repair" processes are called "mismatch repair proficient". These two types of endometrial cancer are likely to be caused by different things (such as inactive genes that would normally protect us against getting a cancer) and may respond differently to treatment with durvalumab. Durvalumab is an antibody (a type of human protein) that works by blocking a naturally occurring substance in the body called PD-L1. Blocking PD-L1 helps the body's immune system to attack cancer cells. Research has shown that durvalumab can help the immune system to slow tumour growth and shrink tumours in some people with cancer.
ANZGOG PI	Assoc Prof Yoland Antill
PI INSTITUTION	Cabrini Health and Monash University
CANCER TYPE	Endometrial
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Durvalumab
LEAD GROUP, COUNTRY	ANZGOG-led national trial
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trial Centre
NUMBER OF SITES	12 ANZ
RECRUITMENT	71 ANZ
FUNDING	AstraZeneca

> *"Suddenly I found myself the PI of a $1m multicentre clinical trial. This is where the partnership of the ANZGOG family and NHMRC Clinical Trials Centre (CTC) came into its own. They looked after contract development and protocol work-up, managed budget negotiations, and coordinated processes for insurance and consent. Support from Dr Peey-Sei Kok (ANZGOG Clinical Fellow) and John Andrews (ANZGOG Program Manager) was invaluable."*
>
> **ASSOC PROF YOLAND ANTILL**

WHAT WAS THE FOCUS OF PHAEDRA?

PHAEDRA was a single-arm phase II trial designed to examine the effect of single-agent durvalumab in women with advanced endometrial cancer. The trial involved two cohorts of women: women with DNA mismatch repair (MMR) proficient and deficient endometrial cancer (as determined by immunohistochemistry testing for MMR proteins).

WHAT DID PHAEDRA FIND?

PHAEDRA demonstrated a significant response to durvalumab in MMR-deficient advanced endometrial cancer and a minimal response in the MMR-proficient tumours.

HOW WILL PHAEDRA CONTRIBUTE TO IMPROVEMENTS IN OUTCOMES FOR WOMEN WITH ENDOMETRIAL CANCER?

PHAEDRA adds to the evidence aiming to drive a change in the standard of care for women with endometrial cancer. It has also contributed to a move towards universal testing of MMR deficiency in women with endometrial cancer.

For many years, women with endometrial cancer thought that chemotherapy was their only option. PHAEDRA has led to an understanding that in advanced disease, chemotherapy does not represent a cure, and that the way forward in improving outcomes is through pre-clinical research and clinical trials of new treatment options.

Trials such as PHAEDRA are opening up new possibilities for the treatment of endometrial cancer. A number of phase III trials are now exploring the use of immunotherapy to induce an immune response in women with MMR-proficient endometrial cancer.

HOW DID ANZGOG CONTRIBUTE TO PHAEDRA?

PHAEDRA was made possible by the teamwork and support of people at ANZGOG and the NHMRC CTC with experience in designing and running high-quality clinical trials.

The MMR proficient arm closed 12 months ahead of recruitment scheduling and the MMR deficient arm was also ahead of schedule. This provided the opportunity – albeit under time pressure – to submit an abstract to ASCO 2019 on the 16-week disease control rate (one of the trial's secondary objectives). With the final patient requiring restaging between Christmas and New Year 2018, a strong team effort meant that the abstract could still be submitted at the beginning of February.

WHAT CAN WE LEARN FROM PHAEDRA?

For a long time, there were no ideas coming forward in endometrial cancer that could be taken forward in clinical trials. This has resulted in treatment options for endometrial cancer lagging behind those for ovarian cancer. PHAEDRA has provided individual and sector-wide learnings about how to design and run a phase II trial in endometrial cancer within a competitive sector.

It also highlights the importance of maintaining a strong independent clinical research sector capable of driving research focused on patient outcomes and not solely influenced by financial drivers.

Assoc Prof Yoland Antill

FUNDRAISING
FOR RESEARCH

ANZGOG holds a commitment to fundraising to maintain a healthy capacity to fund our member's brilliant research ideas, and to ensure financial security for the organisation. Fundraising for research is achieved through bequests, donations, partnerships (campaigns), and philanthropic grants.

ANZGOG has clear programs that communities and organisations can support. Our key area is supporting ANZGOG's new research development which has made it possible for ANZGOG to develop cutting-edge initiatives. For example, Rose Varga chose to leave a bequest to ANZGOG, leaving a legacy that helped launch the OASIS Initiative – a world class collaborative ovarian cancer research program.

Other research advocates, such as Rochelle Fisher, took direct action and raised $33,500 to support an ANZGOG Fund for New Research Grant into a pre-clinical study of leiomyosarcoma of the uterus, a rare endometrial cancer that she was diagnosed with herself. In Western Australia, The Ladybird Foundation – who support breast and gynaecologic cancer research – donated a $30,000 grant to fund a project that is specifically carried out in WA.

ANZGOG also engages with the community through fundraising initiatives such as Go for Gynae and Save the Box, which increased our public presence and engagement and provided more pathways for donors to give to us. 2017 saw the amalgamation of the Women's Cancer Foundation with ANZGOG, increasing our fundraising capacity with the adoption of Team Teal, a fundraising campaign in partnership with the Harness Racing community which has raised over $2 million since 2010. In 2019 ANZGOG launched WomenCan, its new fundraising brand, following consultation with the public and members, and has since gone on to engage the community to fundraise for ANZGOG's research.

Only thanks to our supporters can we continue to foster the new research concepts giving hope to women and those who love them.

"We have an outstanding array of supporters helping us fundraise for research and the conduct of clinical trials at hospitals. These include individual fundraisers, women sharing their stories in the media, on social media and our websites, companies and organisations that run events and fundraisers, thank you all."

ASSOC PROF PHILIP BEALE
ANZGOG CHAIR

WOMENcan FUNDING CANCER RESEARCH
team teal

GO for Gynae

WOMENcan FUNDING CANCER RESEARCH

WOMENcan SAVE THE BOX FUNDING CANCER RESEARCH

CLINICAL TRIALS

STATEC

STUDY	STATEC
TITLE	A randomised trial of non-selective versus selective adjuvant therapy in high risk apparent stage 1 endometrial cancer
SUMMARY	STATEC is a study for women with apparent stage 1 endometrial (womb) cancer at high risk of relapse. The standard treatment for this condition varies within Australia but includes surgery to remove the womb, ovaries and fallopian tubes with or without removal of pelvic lymph glands, and with or without additional treatment with chemotherapy and/or radiotherapy. This study is testing an additional surgical procedure called lymphadenectomy, or lymph gland removal. It involves randomly allocating participants to have either removal of the womb (hysterectomy), ovaries and tubes (with no lymph glands removed), followed by radiation and chemotherapy OR removal of the womb, ovaries and tubes with lymph glands removed to help guide further treatment.
ANZGOG PI	Assoc Prof Alison Brand AM
PI INSTITUTION	Westmead Hospital
CANCER TYPE	Endometrial
PHASE	Phase III
TYPE OF TRIAL	Surgical
LEAD GROUP, COUNTRY	University College London (UCL)-led international trial; ANZGOG-led in Australia and New Zealand
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
NUMBER OF SITES	6 ANZ
RECRUITMENT	48 Total Worldwide, 8 ANZ
FUNDING	NHMRC Project Grant

VIP

STUDY	VIP
TITLE	A Phase II study of intravenous vinorelbine in patients with relapsed platinum resistant or refractory C5 high grade serous, endometrioid, or undifferentiated primary peritoneum, fallopian tube or ovarian cancer
SUMMARY	Vinorelbine is a drug that is currently already being used for treatment of lung and breast cancer. Recently, it has been shown that, based on the analysis of the levels of certain molecules in tumours, ovarian cancers can be consistently classified into 4 molecular subgroups, namely C1, C2, C4 and C5 tumours. The C5 subgroup has been found to be relatively drug resistant with a poor prognosis compared with the other groups. In laboratory studies, vinorelbine has been shown to slow the progression of tumor cells belonging to the C5 subgroup more than tumour cells from other subgroups. In view of this promising data, this clinical study is being carried out to find out if treatment with vinorelbine will have beneficial effects in patients with ovarian/ fallopian tube or peritoneal cancer belonging to the C5 subgroup. In addition, we will also study how specific changes and molecular markers in blood and tumor samples may be used to predict the chance of benefiting from study treatment.
ANZGOG PI	Prof Linda Mileshkin
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Vinorelbine
LEAD GROUP, COUNTRY	National University Hospital, Singapore (NUHS)-led international trial; ANZGOG-led in Australia
SPONSOR	ANZGOG
OPERATING CENTRE	Centre for Biostatistics and Clinical Trials
PLANNED NO OF SITES	6 ANZ
TARGET RECRUITMENT	36 Total Worldwide, 15 ANZ
FUNDING	OASIS Initiative, Baker Foundation Grant

FUND FOR NEW RESEARCH

The Fund for New Research (formally the 'New Research Fund') was established in 2015 to foster new research ideas from ANZGOG members. The initiative has provided funding to support pilot studies, innovative sub-studies, pre-clinical studies with the potential to lead to a clinical trial, and has also encouraged early career researchers to develop new ideas.

> *"In the previous decade we had heard over and over again from our members that they had great ideas, but they had no money to develop their ideas into a clinical trial, and neither did we as an organisation! Establishing the Fund for New Research and the OASIS Initiative really gave us a way of funding these ideas and pilot studies, that we hoped would then provide pilot data that could enable us to go for larger government/pharma funding opportunities."*
>
> **ASSOC PROF ALISON BRAND AM**

The program is made possible by public donations, bequests, and philanthropic grants from charities with shared interests in ANZGOG's research work. It gives donors a unique opportunity to directly contribute to a particular type of research. In recent years, three grants were made possible by donors:

(L-R) Assoc Prof Philip Beale & Dr Paul Cohen at the ANZGOG 2018 ASM

1. **The Ladybird Foundation, WA** – $30,000 grant offered for a project which is primarily carried out in Western Australia with a WA Principal Investigator.
2. **Rochelle Fisher Grant –** $30,000 grant for a study of leiomyosarcoma of the uterus.
3. **Judith Meschke Memorial Gran**t – $50,000 grant for a study of clear cell ovarian cancer.

With this financial support, $631,070 has been awarded to 14 research projects between 2015 and 2020.

YEAR	ANZGOG PI	STUDY	AMOUNT AWARDED
2015	Dr Michelle Wilson	A phase II, open-label, randomised, multi-centre study of neoadjuvant olaparib in patients with platinum sensitive recurrent high grade serous ovarian/peritoneal or fallopian tube cancer (NEO)	$23,633
2016	Dr Paul Cohen	Excisional treatment in women with cervical adenocarcinoma-in-situ (AID): a prospective randomised controlled non-inferiority trial to compare AIS persistence/recurrence after loop electrosurgical excision procedure to cold knife cone biopsy. (EXCISE Pilot)	$50,000
	Assoc Prof Alison Brand AM	Testing individual interventions to optimize perioperative care in ovarian cancer surgery (TIPS Pilot)	$50,000
	Prof Paul Harnett	Production of Wilms tumour protein (WT1) T cells for adoptive cellular therapy of WT1 expressing ovarian cancer.	$50,000
2017	Prof Amanda Spurdle	Molecular and genomic correlations with clinical response to durvalumab in advanced endometrial cancer (PHAEDRA-TR)	$50,000
	Dr Katrin Sjoquist	Understanding resistance and sensitivity to PARP inhibitors in homologous recombination deficient (HRD) high grade serous ovarian cancer; translational research from the EMBRACE clinical trial (EMBRACE-TR)	$48,300
2018	Assoc Prof Tarek Meniawy	Circulating tumour DNA was a biomarker of treatment response for patients with advanced high grade serous ovarian cancer receiving neoadjuvant chemotherapy with and without durvalumab and tremelimumab as part of the iPRIME study (TR-iPRIME)	$49,137
	Dr Prahlad Raninga	Repurpose FDA approved drug to selectively target mutant-p53 high-grade serous ovarian cancer	$50,000
	Assoc Prof Pamela Pollock	Preclinical studies to evaluate biomarkers of response to PARP inhibition in endometrial cancer PDX models	$50,000
2019	Assoc Prof Haryana Dhillon	Conquer fear from ovarian cancer	$50,000
	Dr Prahlad Raninga	Targeting MYC-dependent high-grade serous ovarian cancer via FACT complex inhibition	$50,000
	Dr Genevieve Dall	Generating pre-clinical models for uterine leiomyosarcoma to help direct treatment	$30,000
	Prof John Hooper	Targeting metabolism to improve efficacy of ovarian clear cell carcinoma therapeutic agents	$50,000
	Dr Paul Cohen	Getting the MOST out of follow-up: a randomised controlled trial to compare three-monthly nurse-led telephone follow-up, including monitoring serum CA125 and patient reported outcomes using the MOST (Measure of Ovarian Symptoms and Treatment concerns) with routine clinic-based follow-up, following completion of first-line chemotherapy in patients with epithelial ovarian cancer	$30,000

CLINICAL TRIALS

ICON9

STUDY	ICON9
TITLE	An international phase III randomised study to evaluate the efficacy of maintenance therapy with olaparib and cediranib or olaparib alone in patients with relapsed platinum-sensitive ovarian cancer following a response to platinum-based chemotherapy
SUMMARY	The purpose of this study is to investigate whether we can increase the effectiveness of treatment in ovarian cancer by adding one or two new anti-cancer drugs: cediranib and olaparib. Olaparib is a drug that stops one of the repair chemicals (called PARP-1) from fixing broken pieces of DNA. When it does this, cells can still be repaired by a different DNA repair system if the cells contain a working copy of the genes called BRCA1 and BRCA2. If the cells do not have a working copy of both of these genes, then upon exposure to olaparib the cells suffer considerable DNA damage and self-destruct. Cediranib works in a different way and is considered a 'targeted therapy' rather than a chemotherapy drug. As cancers grow they need to develop their own new blood supply to survive and this development of new blood supply vessels is known as angiogenesis. Cediranib works by slowing or stopping the growth of these new blood vessels which will, we hope, interfere with the cancer's ability to grow and spread to other parts of the body.
ANZGOG PI	Prof Linda Mileshkin
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
PHASE	Phase III
TYPE OF TRIAL	Intervention
DRUG/S	Olaparib, cediranib
LEAD GROUP, COUNTRY	University College London (UCL)-led international trial; ANZGOG-led in Australia and New Zealand
COLLABORATIONS	CCTG, MaNGO, MITO
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	19 ANZ
TARGET RECRUITMENT	618 Total Worldwide, 110 ANZ
FUNDING	Cancer Australia, UCL

SOLACE2

STUDY	SOLACE2
TITLE	A phase II randomised trial comparing immune priming by low dose oral cyclophosphamide plus olaparib versus priming by olaparib alone, prior to combination therapy with olaparib plus durvalumab, versus single agent olaparib alone, in asymptomatic platinum-sensitive recurrent ovarian, fallopian tube or primary peritoneal cancers with homologous recombination repair defects
SUMMARY	The SOLACE2 trial is a multi-centre randomised Phase II investigator-initiated trial with the aim of investigating different strategies to prime the immune system to enhance response to olaparib in women with asymptomatic platinum-sensitive recurrent ovarian, fallopian tube or primary peritoneal high grade serous cancers at the time of the first CA125 serum marker rise. Women are randomised to receive either olaparib or olaparib plus oral cyclophosphamide for three months before being treated with olaparib and durvalumab. A control arm of olaparib only treatment will be used to examine for comparative differences. The study will recruit women with and without BRCA mutations. The primary endpoint of this trial is progression-free survival, with other secondary and extensive translational endpoints.
ANZGOG PI	Prof Clare Scott, Assoc Prof Chee Lee, Prof Michael Friedlander AM
TRANSLATIONAL CHAIR	Prof Magdalena Plebanski
PI INSTITUTION	Peter MacCallum Cancer Centre, St George Hospital, Prince of Wales Hospital
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Olaparib, cyclophosphamide, durvalumab
LEAD GROUP, COUNTRY	ANZGOG-led national trial
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	15 ANZ
TARGET RECRUITMENT	114 ANZ
FUNDING	AstraZeneca

“In ovarian cancer we have not known the enemy and we have made very little progress to now. The clouds have parted in the last few years and I think we have a much better idea of what we are up against.”

PROF DAVID BOWTELL
PRINCIPAL INVESTIGATOR
AUSTRALIAN OVARIAN CANCER STUDY (AOCS)

THE OASIS INITIATIVE

OASIS
Ovarian Cancer Alliance for Signal Seeking Research

New genomic knowledge has radically changed the way we view ovarian cancer. The Ovarian cancer Alliance for Signal-Seeking Research (OASIS) initiative was created to undertake small signal seeking studies that show sufficient evidence of clinical activity to allow larger randomised trials. It aims to be a catalyst for new treatments, stimulate research ideas, and improve treatment outcomes for women with ovarian cancer.

The OASIS research model aims to significantly shorten the cycle of clinical testing by:

- **Speeding Translation:** Strengthen existing links between laboratory and clinical researchers to accelerate the application of research findings,
- **Improving cost-efficiency:** Develop an infrastructure and culture that enables much more cost-effective trials,
- **Developing funding:** Establish a pool of funds, with proper governance oversight, to support the prompt initiation of signal-seeking studies once indicators are identified in the lab.

The initiative was seed funded by philanthropy, and since, has sought funding from pharma, philanthropic grants, and private and public donations. The funding for this initiative has grown from the initial philanthropic seed funding grant of $1.1million to now almost $12million. ANZGOG has conducted six studies since the inception of OASIS (as of June 30, 2020).

“A signal-seeking clinical trial is like sending out a scouting party to map the terrain ahead. These trials are nimble and responsive to new information, showing the way forward for the main group.”

PROF MICHAEL FRIEDLANDER AM
CHAIR – OASIS STEERING COMMITTEE (2015-2020)

“It’s so odd and so awful being 40 and knowing what will kill me. But what makes it even worse is knowing that I’m just one in a long and continuing line of women. Young women, old women, all of us. We’re all walking down the same well-trodden path.

The survival rates for ovarian cancer have changed so little in the last 30 years. The approach we’ve always had to treatments - that one size fits all - just isn’t working. Thirty years and 33,000 women who’ve died have shown us that.

But there is a glimmer of hope. We now know that ovarian cancer is really several different diseases. If we can secure the funding, new trials for these individual diseases can establish specific and better treatment paths for us. In the meantime, we’re waiting. Waiting for an answer; waiting for something new, something better than one size fits all.

And hoping, finally, that well-trodden path we’re taking will make a U-turn.”

VALE BRIDGET WHELAN
OASIS ADVOCATE

CLINICAL TRIALS

MOCCA

STUDY	MOCCA
TITLE	A multicentre phase II randomised trial of durvalumab (MEDI4736) versus physician's choice chemotherapy in recurrent ovarian clear cell adenocarcinomas
SUMMARY	Ovarian clear cell carcinoma (OCCC) is an uncommon sub-type of ovarian cancer that makes up 5-8% of ovarian cancers in Australia. However, in Asian women, nearly 25% of ovarian cancers are OCCC. Women diagnosed with OCCC tend to be younger and more likely to be diagnosed with earlier stage disease (Stage I) and have a good prognosis if Stage 1. However, patients with OCCC with advanced stage disease typically have much lower response to platinum based chemotherapy compared to other types of ovarian cancer and a worse prognosis. There is preliminary data to suggest that OCCC may respond to immunological therapies with drugs such as durvalumab and this needs to be confirmed in a larger trial. The purpose of this trial is to determine if a drug called durvalumab will improve progression free survival, when compared to physician's choice chemotherapy, in patients with OCCC. Overall survival, quality of life and adverse events will also be studied. Patients will be randomised in a 2:1 ratio to either receive durvalumab or physician's choice chemotherapy. The chemotherapy selected for treatment will be standard treatment. Patients who get chemotherapy will have be able to durvulumab if they progress.
ANZGOG PI	Prof Michael Friedlander AM
PI INSTITUTION	Prince of Wales Hospital
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Durvalumab
LEAD GROUP, COUNTRY	National University Hospital, Singapore (NUHS)-led international trial; ANZGOG-led in Australia
COLLABORATIONS	Korean Gynecologic Oncology Group (KGOG)
SPONSOR	ANZGOG
OPERATING CENTRE	Centre for Biostatistics and Clinical Trials
NUMBER OF SITES	3 ANZ
RECRUITMENT	46 Total Worldwide, 9 ANZ
FUNDING	OASIS Initiative, NUHS

PRECISE

STUDY	PRECISE
TITLE	A phase II, signal-seeking trial of the clinical benefit rate associated with pamiparib in subjects with germline or somatic BRCA1/2 high grade serous ovarian cancer or carcinosarcoma who have progressed on P-gp substrate chemotherapy or PARP inhibitors with the presence of an ABCB1 fusion and the absence of a BRCA1/2 reversion
SUMMARY	High-grade serous ovarian cancer (HGSOC) is the most common type of ovarian cancer and is associated with poor survival. Research has identified a subgroup of HGSOC that has developed resistance to treatment because of abnormalities in genes that develop after exposure to chemotherapy. These gene abnormalities can now be detected in patients that are likely to be resistant to certain chemotherapies or oral PARP inhibitors (PARPi) through blood tests and tumour biopsies or ascitic fluid. The PRECISE study is the first study to select a personalised treatment for HGSOC patients with BRCA1/2 mutations using a new PARPi called pamiparib based on on gene tests for patients with the hope to improve patient outcomes.
ANZGOG PI	Dr Ali Freimund
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Pamiparib
LEAD GROUP, COUNTRY	ANZGOG-led national trial
SPONSOR	ANZGOG
OPERATING CENTRE	Centre for Biostatistics and Clinical Trials
PLANNED NO OF SITES	7 ANZ
TARGET RECRUITMENT	40 ANZ (200 Screened)
FUNDING	BeiGene, OASIS Initiative, Perpetual Grant

CLINICAL TRIALS

iPRIME

STUDY	iPRIME
TITLE	A phase II study of durvalumab (MEDI14736) and tremelimumab in combination with neoadjuvant carboplatin and paclitaxel in newly diagnosed women with advanced high grade serous ovarian, fallopian tube and peritoneal cancers
SUMMARY	This study will evaluate the safety and efficacy of durvalumab and tremelimumab in combination with first line chemotherapy in advanced ovarian cancer. Importantly, the study will have a strong translational backbone referred to as TRiPRIME, aiming to evaluate the immune, histopathological and molecular correlates of response to the chemotherapy immunotherapy combination. It includes mandatory pre-treatment biopsies to allow comprehensive molecular classification, network analysis from gene expression data, immune infiltrate assessment, peripheral blood +/- ascites for analysis of immune markers by flow or mass cytometry, and circulating tumour DNA. The ultimate aim is to optimise the selection of patients who are more likely to benefit from immunotherapy in combination with standard platinum-based chemotherapy and this study will lay the foundations for this.
ANZGOG PI	Assoc Prof Tarek Meniawy
PI INSTITUTION	Sir Charles Gairdner Hospital, Linear Clinical Research, St John of God Subiaco Hospital
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Durvalumab, tremelimumab, carboplatin, paclitaxel
LEAD GROUP, COUNTRY	ANZGOG-led national trial
SPONSOR	ANZGOG
OPERATING CENTRE	Centre for Biostatistics and Clinical Trials
PLANNED NO OF SITES	10 ANZ
TARGET RECRUITMENT	75 ANZ
FUNDING	AstraZeneca, OASIS Initiative

"The ovarian preceptorship was a great forum to learn about the trials that have shaped our current standards of care for patients with ovarian cancer. I highly encourage young clinicians to join in this multidisciplinary preceptorship to learn from each other."

DR MICHAEL BURLING
GYNAECOLOGICAL ONCOLOGIST

DEVELOPING THE NEXT GENERATION

ANZGOG's second decade has focussed on providing early-career researchers with opportunities to further their gynaecological cancer research education. ANZGOG's education events are intellectually stimulating opportunities, as they foster an interdisciplinary approach to the diagnosis and management of gynaecological cancers. These opportunities create meaningful engagement with younger ANZGOG members and help to develop future leaders in the gynaecological cancer space.

ANZGOG's inaugural Preceptorship was held in November 2017, focusing on ovarian cancer. Supported by Roche Australia, the workshop focused on ovarian cancer and all therapeutic approaches, and a review of the most important papers of the last 15 years.

"The development of the preceptorships at our ASMs really engaged our younger clinicians. Prior to this, we had a real lack of engagement from them. At first, we'd mistakenly thought "If we build it, they will come" but it was more like "If you offer an outstanding educational experience, then they will come" and they did, in droves! Having the Preceptorships embedded in the ASM, meant that they got to see, often for the first-time, what type of organisation ANZGOG was; how collegiate it was, what it hoped to accomplish, and they became much more enthusiastic as a result of this. The engagement of younger members will ensure that ANZGOG can continue on, long after the current leaders have left. They are the future of ANZGOG."

ASSOC PROF ALISON BRAND AM
CHAIR | ANZGOG (2012-2018)

The meeting stimulated great interest from Fellows, Registrars, Advanced Trainees and research students. Due to its success, the preceptorships later became a staple of ANZGOG's annual educational programs.

"The ANZGOG preceptorships are about more than just learning up-to-date, best practice approaches to the management of gynaecological cancers. They are an opportunity to collaborate, to learn from one another, to advocate for women with gynaecological malignancies, and to become excited about the future of our professions."

DR MICHAEL KRASOVITSKY,
MEDICAL ONCOLOGIST

Since the inaugural Preceptorship, ANZGOG has organised numerous education events for its members, including workshops and webinars, often supported by Pharma partners.

EARLY-CAREER RESEARCHER ATTENDEES AT ANZGOG ASMS

In addition to ANZGOG's education program, early-career researchers can also begin contributing to ANZGOG's research framework by submitting their ideas to the Fund for New Research program, as well as applying to join one of ANZGOG's research committees.

CLINICAL TRIALS

TIPS

STUDY	TIPS
TITLE	Testing individual interventions to optimise perioperative care in ovarian cancer surgery
SUMMARY	Enhanced recovery after surgery (ERAS) is a multimodal perioperative pathway designed to achieve early recovery after major surgery by reducing physiological perioperative stress and organ dysfunction. By targeting factors that may delay recovery after surgery such as prolonged perioperative fasting, delayed mobilisation and use of bowel prep and utilising interventions such as avoidance of opioids, early mobilisation and early feeding, we enable patients to regain normal function quicker, spend less time in hospital and minimize the likelihood of complications. ERAS interventions have been widely studied in colorectal surgery and guidelines for gynaecologic oncology procedures have also been published. However, most of the interventions suggested have not been studied extensively in ovarian cancer patients and those that have, have weaknesses in their study design. Surgery for advanced ovarian cancer is complex and often involves multiple procedures including bowel resection and upper abdominal surgery. Consequently, it may be associated with high risk of peri- and postoperative complications and prolonged hospital stay. Of all gynaecological cancer patients, patients with advanced ovarian cancer are likely to benefit most from ERAS interventions. The aim of this proof of concept study is to assess whether two specific ERAS interventions - the preoperative administration of a carbohydrate-rich drink and the pain medication pregabalin given prior to start of anaesthesia - are safe, improve wellbeing and hasten recovery after surgery in ovarian cancer patients. If successful, this study will generate preliminary data to support the development of an international, multicentre, randomised trial to reliably determine the feasibility, activity and effectiveness of ERAS interventions in advanced ovarian cancer.
ANZGOG PI	Assoc Prof Alison Brand AM
PI INSTITUTION	Westmead Hospital
CANCER TYPE	Ovarian
TYPE OF TRIAL	Intervention
DRUG/S	Preoperative carbo-loading (Nutricia PreOp Drink) and perioperative pregabalin (Lyrica ®)
LEAD GROUP, COUNTRY	ANZGOG-led in Australia and New Zealand
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	6 ANZ
TARGET RECRUITMENT	60 ANZ
FUNDING	Australian Society of Gynaecological Oncologists (ASGO), ANZGOG Fund for New Research 2016

STICs and STONEs

STUDY	STICs and STONEs
TITLE	A randomised phase II double-blind placebo-controlled trial of acetylsalicylic acid (ASA) in prevention of ovarian cancer in women with BRCA 1/2 mutations
SUMMARY	Women with a BRCA1 or BRCA2 gene abnormality are at increased risk of ovarian and fallopian tube cancers and often have their ovaries and tubes removed to prevent cancer. Microscopic cancers are sometimes seen at the time of this surgery. Some studies have suggested aspirin might reduce the risk of developing ovarian and fallopian tube cancers, but this is uncertain because the design of the previous studies was not optimal. The STICs and STONEs study will assign women with a BRCA1 or BRCA2 gene abnormality to daily aspirin or placebo for at least 6 months and no more than 24 months before their preventive surgery. We expect to see fewer cancers at the time of preventive surgery in the group of women that is assigned to aspirin compared with those assigned placebo. The study will provide a better understanding of how ovarian and fallopian tube cancers start and whether aspirin might be a useful prevention agent.
ANZGOG PI	Prof Kelly-Anne Phillips
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Acetylsalicylic acid (ASA; aspirin)
LEAD GROUP, COUNTRY	Canadian Cancer Trials Group (CCTG)-led international trial, ANZGOG-led in Australia
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	6 ANZ
TARGET RECRUITMENT	414 Total Worldwide, 70 ANZ
FUNDING	NHMRC Clinical Trial Centre Project Grant, Support from CCTG

Survivors Teaching Students Regional Coordinator (WA) Clare, who presents her story with her husband and caregiver, Mark.

SURVIVORS TEACHING STUDENTS

SURVIVORS TEACHING STUDENTS
Saving Women's Lives®

ANZGOG has developed an outstanding consumer-led volunteer program that educates health professional students about ovarian and other gynaecological cancers. It is part of our ongoing commitment to consumer engagement and communication.

Survivors Teaching Students® (STS) brings the faces and voices of ovarian cancer survivors and caregivers into the classrooms of future doctors to teach them about the diseases. Survivors, through their own personal experiences, are in a unique position to help students become more sensitive to the risks and symptoms of ovarian cancer, to encourage detection and earlier diagnosis when they go into practice.

2017-2020:

5000+
STUDENTS ENGAGED THROUGH EDUCATION SESSIONS

162
VOLUNTEERS
trained on the STS program

17
WITH UNIVERSITIES AND THEIR SCHOOLS

> *"Our volunteers, women and caregivers that share their stories to help our doctors, nurses and allied health professionals of the future understand the experience of ovarian cancer. They teach them to be alert to the signs and symptoms of ovarian cancer and practice important communication and listening skills necessary when talking with people about a cancer diagnosis, prognosis and treatments."*
>
> **ASSOC PROF PHILIP BEALE**
> **ANZGOG CHAIR**

Bronwyn Grout was an extremely important part in bringing STS to Australia, after stumbling upon the program in the U.S. After returning to Australia, Bronwyn was determined to give women like her the same opportunity that she had at STS, so she reached out to ANZGOG. A few years later in 2017, the program was awarded $120,000 from the Australian Government through Cancer Australia's Supporting People with Cancer Grant initiative, which signalled the beginning of STS in Australia.

> *"I wanted the women in Australia impacted by ovarian cancer to have the same voice I had. From 2014, I knocked on doors to bring the STS program to Australia and in 2016, the perfect home was found with ANZGOG. The program has quickly surpassed all my hopes.*
>
> *The program has created an incredible community of wonderful caring women and men, passionately raising awareness of ovarian cancer amongst the medical professionals of the future."*
>
> **BRONWYN GROUT**

The STS program has fostered a strong, passionate community of survivors and caregivers, several of whom have engaged with ANZGOG's fundraising initiatives and even joined the Consumer Research Panel to help inform our research. It is a testament to ANZGOG's strong ties with consumers and continues to engage more survivors and educate more students year by year.

Dr George Au-Yeung
Principal Investigator of IGNITE

CLINICAL TRIALS

IGNITE

STUDY	IGNITE
TITLE	A phase II signal-seeking trial of adavosertib (AZD1775) targeting recurrent high grade serous ovarian cancer (HGSC) with cyclin E1 (CCNE1) over-expression with and without gene amplification
SUMMARY	This research project is testing a new treatment called adavosertib. Adavosertib is an inhibitor of WEE1, which is a protein tyrosine kinase. Protein tyrosine kinases work by reducing the growth of tumours by blocking some of the enzymes needed for cell growth. By blocking these enzymes, adavosertib, may help stop the growth of cancer cells. The purpose of this research project is to test how effective adavosertib treatment is for patients with relapsed high grade serous or endometrioid ovarian cancer with particular genetic faults, which alter how tumour cells respond to treatment.
ANZGOG PI	Dr George Au-Yeung
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Ovarian
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Adavosertib
LEAD GROUP, COUNTRY	ANZGOG-led national trial
SPONSOR	ANZGOG
OPERATING CENTRE	Centre for Biostatistics and Clinical Trials
PLANNED NO OF SITES	11 ANZ
TARGET RECRUITMENT	96 ANZ (350 Screened)
FUNDING	AstraZeneca

STUDY COORDINATORS COMMITTEE

ANZGOG's Study Coordinators Committee (SCC) was developed to inform the organisation's research portfolio. Since its inception, the committee has provided ANZGOG researchers with operational insights and kept the organisation updated on site capacity, at both an individual and wider health network level.

Committee members represent the different personnel at clinical trial sites – Research Nurses, Data Managers and Study Coordinators, and offer a unique perspective surrounding the conduct of clinical research. In their role, members also identify and facilitate training and development needs to further enhance the efficiency and effectiveness of site staff supporting ANZGOG's research portfolio. Committee members represent most States and Territories across Australia, as well as New Zealand and regional health settings. Furthermore, SCC members have been actively engaged with ANZGOG's operations and development though representation on various committees including the ASM Organising Committee, RAC, OASIS, QA, and having its Chair as a member of the ANZGOG Board.

During its many years of operation, the committee has been able to provide an integral voice during the development, and subsequent review, of ANZGOG clinical trials, and has helped finesse the operational aspects of the trials being conducted. The members have, over the years, fostered a close relationship with the ANZGOG Consumer Research Panel which has enhanced understanding of the value of research from different perspectives.

> *"Committee members have contributed their ideas and understanding of the clinical research landscape to enhance education, improve quality and efficiency of trial management and identify pathways to growth and development, not only for the benefit of its own workforce but for ANZGOG undertakings as a whole.*
>
> *The composition of the committee has changed over the years, with some individual members moving on, and new members bringing fresh ideas, perspectives and skills to the group keeping it a valuable, dynamic resource as ANZGOG also continues to evolve and grow."*

SUE BREW
CHAIR | STUDY COORDINATORS COMMITTEE (2011-2020)
ANZGOG DIRECTOR (2011-2019)

(L-R) Catherine Adams & Sue Brew at the ANZGOG 2017 ASM

SCC members (L-R) Meghan Leigh and Donna Long at the 2019 ANZGOG Research Development Day.

CLINICAL TRIALS

AtTEnd

STUDY	AtTEnd
TITLE	Phase III double-blind randomised placebo controlled trial of atezolizumab in combination with paclitaxel and carboplatin in women with advanced/recurrent endometrial cancer
SUMMARY	The AtTEnd clinical trial is for women with advanced endometrial cancer (Stage IV or Stage III if surgery is not possible) and will assess whether the use of the immune therapy atezolizumab is of additional benefit to our current first line chemotherapy combination (carboplatin and paclitaxel). The trial is a Phase III study with two separate arms: two thirds of women will receive the additional immune therapy and one third will receive a placebo infusion. Neither the patient nor their treating doctor will know which arm of the study she has been randomised to, which is known as a blinded randomisation. For most women with endometrial cancer, immune therapy alone is not an effective way of treating endometrial cancer. However by adding chemotherapy this may improve the chance of immune therapy stimulating the body's own immune system to fight and destroy the cancer cells.
ANZGOG PI	Assoc Prof Yoland Antill
PI INSTITUTION	Cabrini Health and Monash University
CANCER TYPE	Endometrial
PHASE	Phase III
TYPE OF TRIAL	Intervention
DRUG/S	Atezolizumab/placebo in combination with platinum-taxol chemotherapy
LEAD GROUP, COUNTRY	Mario Negri Gynecology Oncology Group (MaNGO)-led international trial; ANZGOG-led in Australia and New Zealand
COLLABORATIONS	AGO, AGO-AUST, GEICO, JGOG, NCRI, SAKK
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	15 ANZ
TARGET RECRUITMENT	550 Total Worldwide, 40 ANZ
FUNDING	MaNGO

CLINICAL TRIALS

EmQUEST

STUDY	EmQUEST
TITLE	Identifying factors which predict for health-related quality of life deficits and increased symptom burden in women who have been treated for endometrial cancer
SUMMARY	The EmQUEST study will aim to identify factors which predict for health-related quality of life deficits and increased symptom burden in women who have been treated for endometrial cancer. We know that after treatment for endometrial cancer some women can have a number of unique health needs, which can be difficult to cope with. We hope to gather responses from women in Australia and abroad, to gain a meaningful cross-sectional assessment of the issues that most affect women who have been treated for endometrial cancer. This will help us to improve treatments, identify women most at risk of significant side effects and plan better services to address unmet needs.
ANZGOG PI	Prof Linda Mileshkin
PI INSTITUTION	Peter MacCallum Cancer Centre
CANCER TYPE	Endometrial
LEAD GROUP, COUNTRY	ANZGOG-led study in collaboration with Peter MacCallum Cancer Centre
TARGET RECRUITMENT	200-500
FUNDING	Peter MacCallum Cancer Foundation Grants 2019

“The TR-ANZGOG initiative has not come a moment too soon, with a raft of new ANZGOG trials due to open, and with the anticipated increased reliance on biospecimens and molecular pathology. TR-ANZGOG will assist investigators with biospecimen aspects of trial protocols, ensuring adequate skills and resources are available to fully leverage the value of biospecimens for translational research.”

PROF ANNA DEFAZIO
CHAIR | TR-ANZGOG STEERING COMMITTEE

WORLD CLASS TRANSLATIONAL RESEARCH IN GYNAECOLOGICAL CANCERS

In 2013, ANZGOG set itself the goal of building capacity for translational research through the development of a national gynaecological cancer biobank within the next 5 years, as part of the strategic plan. A working group led by translational researcher and ANZGOG Member, Prof Anna DeFazio, was established to explore options for the biobank and identify the steps needed to achieve this. Consequently, the new initiative, which was named Translational ANZGOG, or 'TR-ANZGOG' was established.

“TR-ANZGOG will help us to investigate why the drug tested in the trial works, or doesn't work, at an individual patient level.”

PROF ANNA DEFAZIO
CHAIR | TR-ANZGOG STEERING COMMITTEE

TR-ANZGOG is a world-class translational research initiative designed to add value to ANZGOG clinical trials for women with gynaecological cancers.

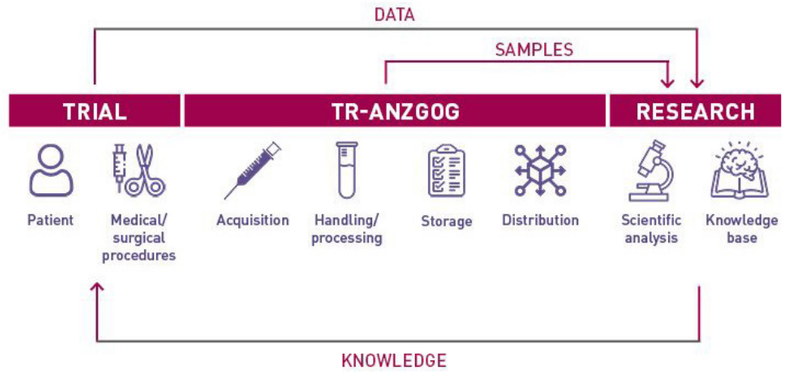
Translational research describes the process where scientific discoveries in the laboratory translate into improved practice in the clinic. TR-ANZGOG supports the collection and use of biospecimens (such as blood and tissue) associated with ANZGOG trials for current and, with consent, future research. This will maximize the contribution made by women participating in ANZGOG trials.

One of TR-ANZGOG's key goals is to help find biomarkers that are associated with good response to trial drugs, and, if response is not as good as expected, to find out why.

“It is outstanding to see the support for this project throughout the organisation.”

ASSOC PROF PHILIP BEALE,
CHAIR | ANZGOG

The key elements needed to integrate TR-ANZGOG into future ANZGOG trials were established in 2020. TR-ANZGOG will now be a core pillar of our trial activity and is primed to be embedded in ANZGOG trials as of 2021, creating a seamless interface between our translational and clinical research agendas.



ANZGOG
COLLABORATIVE TRIALS

CLINICAL TRIALS

PeNTAGOn

Collaborations - PeNTAGOn was a collaborative study, led by Peter MacCallum Cancer Centre in collaboration with ANZGOG and Psycho-oncology Co-operative Group (PoCoG).

STUDY	PeNTAGOn
TITLE	A nurse-led psychosocial intervention with peer support to reduce the needs in women being treated with radiotherapy for gynaecological oncology: a RCT.
SUMMARY	The study aims to improve psychosocial outcomes for women receiving radiotherapy for gynaecological cancer. It will also provide much-needed information about the experience and impact of this treatment. The intervention is a support program that includes four consultations with a specially trained nurse before treatment, in the middle of treatment, at the end and 2 weeks post radiotherapy. This is combined with four telephone calls from a trained peer volunteer (a woman who herself has experienced radiotherapy for gynaecological cancer). All participants complete sets of questionnaires measuring psychosocial needs, quality of life and physical and psychological well-being.
ANZGOG PI	Prof Penelope Schofield
PI INSTITUTION	Peter MacCallum Cancer Centre and Swinburne University
CANCER TYPE	Any gynaecological cancer
LEAD GROUP, COUNTRY	Peter MacCallum Cancer Centre
COLLABORATIONS	ANZGOG and Psycho-oncology Co-operative Group (PoCoG)
OPERATING CENTRE	Peter MacCallum Cancer Centre
NUMBER OF SITES	7 ANZ
RECRUITMENT	318 ANZ
FUNDING	Cancer Australia/Beyond Blue, NHMRC Project Grant

CLINICAL TRIALS

feMMe

Collaborations - feMMe was led by the Queensland Centre for Gynaecological Cancer (QCGC) in collaboration with the University of Queensland and Queensland University of Technology. ANZGOG supported this study by providing access to its consumer representative group for their insights.

STUDY	feMMe
TITLE	A phase II randomised clinical trial of mirena® ± metformin ± weight loss intervention in patients with early stage cancer of the endometrium
SUMMARY	feMMe aims to treat women with endometrial cancer less-invasively through the use of the Mirena, an intra-uterine device. This is the same device that is commonly used as a contraceptive (the IUD). Metformin is the most widely used anti-diabetes drug in the world and evidence suggests it is also a powerful anti-cancer drug. feMMe aims to treat endometrial cancer by loading the Mirena with Metformin; this treats cancer from inside the uterus. This is a far less invasive treatment than a radical hysterectomy, and allows at-risk women to avoid the complications and side effects associated with surgery. It also allows women to retain their reproductive organs. The causal link between endometrial cancer and obesity is undeniable. Weight loss interventions are feasible and safe and are already being implemented by gynaecological oncologists to make women eligible for surgery. This study targets a steadily increasing population of morbidly obese, young or co-morbid patients with early endometrial cancer. The gains of a successful project will include the reduction of hospital bed days, radical surgery, surgical complications and their associated costs. It will allow an increasing number of women to maintain their fertility and have children.
ANZGOG PI	Prof Andreas Obermair
PI INSTITUTION	Queensland Centre for Gynaecological Cancer, University of Queensland
CANCER TYPE	Endometrial
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Mirena ®, metformin
LEAD GROUP, COUNTRY	Queensland Centre for Gynaecological Cancer and ANZGOG-led national trial
OPERATING CENTRE	Queensland Centre for Gynaecological Cancer
NUMBER OF SITES	15 ANZ
RECRUITMENT	165 ANZ
FUNDING	Lord Mayors Community Trust, UQ Academic Title Holders Grant, Cherish Women's Cancer Foundation, RBWH Foundation, Cancer Australia

> *"ANZGOG is a hugely important organisation and it is great that Australasian gynaecological oncology researchers have access to it. I am hopeful that ANZGOG will continue to strengthen in capacity and influence as a key part of the vibrant community of investigator-driven gynaecological cancer research in Australasia and internationally."*
>
> **PROF ANDREAS OBERMAIR**

WHAT IS THE FOCUS OF feMMe?

feMMe is a three-arm Phase II randomised trial examining the effect of Mirena® ± metformin ± weight loss in women with early stage endometrial cancer or endometrial hyperplasia with atypia.

feMMe is led by the Queensland Centre for Gynaecological Cancer (QCGC) and has recruited 165 patients across 15 sites in Australia and New Zealand.

WHY IS feMMe IMPORTANT AND HOW MIGHT IT CONTRIBUTE TO IMPROVEMENTS IN OUTCOMES FOR WOMEN WITH ENDOMETRIAL CANCER?

The current standard of care for early endometrial cancer is a total hysterectomy. While effective, hysterectomy may not be suitable for some women. This includes younger women who want to have children and women with co-morbidities for whom surgery is unsafe. Some women may also have a preference not to have surgery.

feMMe aims to generate evidence that will allow women with early stage endometrial cancer to be offered an alternative to surgery as first-line treatment.

> *"Endometrial cancer is typically under-researched when compared with its incidence and burden of disease. QCGC has a growing track record and reputation in endometrial cancer research and over time we have seen this picture changing. Trials that were considered as too ambitious 15 years ago are now being taken forward. The importance of endometrial cancer research is becoming increasingly recognised and it is good to see groups such as ANZGOG strengthening their interest and support in this space."*
>
> **PROF ANDREAS OBERMAIR**

Mirena® is an intrauterine device used for contraception, treatment of heavy menstrual bleeding, and to prevent thickening of the endometrium during oestrogen hormone replacement therapy.

Metformin is a weight-loss medication approved for the treatment of diabetes.

WHAT VALUE DOES ANZGOG BRING?

ANZGOG provided access to its consumer group, facilitating important consumer insight to inform and develop the trial and trial questions.

In the field of gynaecological oncology research, ANZGOG brings start-up funding, and reassurance to potential funders of the quality of the research that will be undertaken. This is a valuable and strategic tool that adds value and increases the reputation of trials.

ANZGOG also provides access to an international network of like-minded collaborative trials groups and researchers with whom ANZGOG has steadily built a strong reputation.

FUTURE DIRECTIONS

Investigator-led research provides the opportunity to explore important clinical questions that will not be funded by industry.

It is important within clinical research for PIs to develop their own groups and networks, ensuring innovation, flexibility and agility. ANZGOG recognises the value of such flexibility while providing infrastructure, support and networks when needed.

CLINICAL TRIALS

VELIA

Collaborations - VELIA was a collaborative study, led by AbbVie/Gynecological Oncology Group (GOG) internationally and by ANZGOG in Australia and New Zealand.

STUDY	VELIA
TITLE	A phase III placebo-controlled study of carboplatin/paclitaxel with or without concurrent and continuation maintenance veliparib (PARP inhibitor) in subjects with previously untreated stages III or IV high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer
SUMMARY	The purpose of this study is to compare the combination of carboplatin, paclitaxel and veliparib to carboplatin and paclitaxel alone followed by continued therapy with veliparib/placebo alone, to determine if it slows the progression of cancer. Additional goals include determining whether the addition of veliparib to chemotherapy improves or delays the return of symptoms from ovarian cancer and the side effects that may occur with the addition of veliparib to chemotherapy.
ANZGOG PI	Prof Michael Friedlander AM
PI INSTITUTION	Prince of Wales Hospital
CANCER TYPE	Ovarian
PHASE	Phase III
TYPE OF TRIAL	Intervention
DRUG/S	Carboplatin, paclitaxel, veliparib
LEAD GROUP, COUNTRY	AbbVie/Gynecological Oncology Group (GOG)-led international trial; ANZGOG-led in Australia and New Zealand
COLLABORATIONS	Participating sites in Israel, Korea, Spain, UK, Brazil, Japan, Denmark, Poland
SPONSOR	AbbVie
OPERATING CENTRE	AbbVie
NUMBER OF SITES	19 ANZ
RECRUITMENT	1140 Total Worldwide, 75 ANZ
FUNDING	AbbVie

CLINICAL TRIALS

EMBRACE

Collaborations – The EMBRACE study is a collaboration between Breast Cancer Trials (BCT), ANZGOG, the Genomic Cancer Clinical Trials Initiative (GCCTI) and the NHMRC Clinical Trials Centre, at the University of Sydney (the CTC).

STUDY	EMBRACE
TITLE	A Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient metastatic breast and relapsed ovarian cancer in patients with germline mutations in BRCA1 and BRCA2
SUMMARY	This study is testing olaparib, in homologous recombination (HR) deficient metastatic breast and relapsed ovarian cancer in patients who do not have hereditary mutations in breast cancer susceptibility gene 1 and gene 2 (BRCA1 and BRCA2). All study participants will take olaparib 300 mg orally twice daily until disease progression or unacceptable toxicity. Assessments for safety and efficacy will be followed up for a minimum of six months. Olaparib is a type of drug called a PARP inhibitor. It has been approved overseas and in Australia to treat ovarian and breast cancer in women with inherited changes in their BRCA1 or BRCA2 genes. There is strong evidence to suggest that olaparib will also work in people who do not have any inherited changes in BRCA genes, but whose cancers have homologous recombination (HR) deficiency. Cancer cells with HR deficiency have defects in their ability to repair themselves and are not able to keep their DNA healthy. The purpose of this study is to assess whether olaparib is effective in treating advanced ovarian and breast cancer in people who do not have inherited changes in their BRCA genes, but whose cancers have HR deficiency.
ANZGOG PI	Dr Katrin Sjoquist
PI INSTITUTION	NHMRC Clinical Trials Centre, St George Hospital
CANCER TYPE	Ovarian and Breast
PHASE	Phase II
TYPE OF TRIAL	Intervention
DRUG/S	Olaparib
SPONSOR	The University of Sydney
OPERATING CENTRE	NHMRC Clinical Trials Centre
PLANNED NO OF SITES	12 ANZ
TARGET RECRUITMENT	60 ANZ
FUNDING	Cancer Australia

EDEN RESEARCH INITIATIVE

The ANZGOG Endometrial Cancer (EDEN) Research Initiative Steering Committee was established in 2020-2021 to consider the best approach to achieving the strategic direction for ANZGOG's commitment in further developing its endometrial cancer clinical trials portfolio. The EDEN Steering Committee, Chaired by Prof Linda Mileshkin with Deputy Chair Assoc Prof Alison Brand AM, identified 5 key areas of focus for the initiative as a whole:

RISK ASSESSMENT AND PREVENTION (INCL OBESITY) EARLY DETECTION AND SURGICAL ISSUES

SURVIVORSHIP, SURVEILLANCE AND REHABILITATION

ADJUVANT THERAPIES & RELAPSED DISEASE

BASIC AND TRANSLATIONAL RESEARCH

FUNDING AND PATIENT ADVOCACY

Each of these areas of focus are being developed through collaborative consultation with a group of 60+ volunteer ANZGOG members.

The Steering Committee will drive the strategy for the research and work closely with the Uterine Tumour working Group who will assist investigators to develop their studies in and will engage ANZGOG members, public, philanthropic and pharma funders, as well as local and global collaborators of ANZGOG to achieve the Initiative's goals.

> *"Despite being the most common gynaecological cancer in Australia and New Zealand, endometrial cancer has long been the "poor cousin" when compared to ovarian cancer. The ANZGOG EDEN initiative is unique in that it aims to focus research activity on all aspects of endometrial cancer, from prevention and risk assessment to novel treatments of early and late-stage disease, as well as advocacy, awareness, and early detection."*

ASSOC PROF ALISON BRAND AM
DEPUTY CHAIR – EDEN STEERING COMMITTEE

LOOKING FORWARD

Actively sharing our learnings to impact on clinical and research practice is vital to improving life for women with a gynaecological cancer. ANZGOG is very focused on how we can translate the results of our research and drive excellence in Australian and New Zealand clinical research over the coming years.

Leadership in investigator-led research is supported by deepening further our strong collaborative links and ensuring our organisation capacity and capability is aligned to provide a robust structure to deliver world-class studies. Globally, we are maintaining and building on our international partnerships, working with groups in many different countries to ensure the relevance, vibrancy, and impact of our research agenda.

Fostering the education and involvement in research of our Fellows and early career researchers is critical to the future of ANZGOG. We will continue to partner with philanthropy and pharma to deliver member, university, and public-facing education.

Nimble, cost effective trial operations need to be supported by smart organisational structures and quality operating units. We remain focused on building a network of trial support organisations and our network of TR-ANZGOG laboratories is growing to support translational activities. Our collaborative network of members research institutes, oncology clinics and satellite sites across the country are enabling effective and efficient patient participation in our clinical trials.

We are strengthening research idea development with initiatives in ovarian, endometrial and translational research, along with a renewed focus on cervical, vaginal and vulval research including through international collaborations – bringing new research to Australia. Our strong member volunteer contribution to research working groups, steering committees and the peak Research Advisory Committee is hard-working and involves the significant support of our Consumer Research Panel, who are passionate about taking part in research development from the idea to trial completion.

ANZGOG's membership continues to grow and as our research work develops, we are seeking out new specialities helping to treat women in the clinic and people working in research institutes across the country who are helping to pioneer new discoveries.

Remaining focused on financial stability is vital to bring members concepts to life in clinical trials. Fundraising for research is intrinsic across the organisation, whether it is our public and philanthropic fundraising team at WomenCan; our research unit in pharma and government grant applications; or our education team seeking support for our education activities - all are focused on finding funds to support our strategic goals.

ANZGOG continues to grow and with that comes an increased focus on impact through our research.

ASSOC PROF PHILIP BEALE
CHAIR | ANZGOG
AS AT JUNE 2021

Improving life for
women through
cancer research

The Australia New Zealand Gynaecological Oncology Group (ANZGOG)
is the peak national gynaecological cancer research organisation for Australia and New Zealand.
We are recognised as a world leader and collaborative partner in clinical trials research.

The Australian Business Number (ABN) is 69 138 649 028.
The Australian Company Number (ACN) is 138 649 028.
ANZGOG is an Australian public company limited by guarantee. ANZGOG is endorsed as a deductible gift recipient under Section 30-15 of the Income Tax Assessment Act 1997.

FUNDING CANCER RESEARCH

WomenCan is a trading name of ANZGOG and conducts fundraising for ANZGOG's research, awareness and education activities.

ANZGOG.ORG.AU **WOMENCAN.ORG.AU**

@WomenCanFund @anzgog @WomenCanFundraising