

CLINICAL TRIALS 2019-2020



Improving life for
women through
cancer research

Current Clinical Trials

TRIALS RECRUITING as at June 30 2020

*Several studies experienced delays in screening/recruitment due to COVID-19

ENDOMETRIAL

Study	EmQUEST
Title	Identifying factors which predict for health-related quality of life deficits and increased symptom burden in women who have been treated with endometrial cancer.
Principal Investigator	Prof Linda Mileshtkin
Collaborations	Initiated in Australia by ANZGOG in collaboration with Peter MacCallum Cancer Centre
Funding	Peter MacCallum Cancer Foundation Grants 2019
Study Milestones	Planned Sample Size: 200-500
Contact	Nikki.Burdett@petermac.org
Summary	<p>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.</p> <p>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.</p>



Prof Linda Mileshtkin
Principal Investigator

Current Clinical Trials

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OVARIAN

Study	ECHO
Title	A Phase III randomised, controlled trial of exercise during chemotherapy for patients commencing first line treatment for ovarian cancer.
Principal Investigator	Prof Sandi Hayes
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC and Griffith University
Funding	Cancer Australia/Cancer Council Australia Recruitment support from World Cancer Research Fund (WCRF) Cancer Australia
Study Milestones	Planned Sample Size: 500 Planned Number of Sites: 9 Accrual: 268 patients 8 sites
Contact	echo@ctc.usyd.edu.au
Summary	<p>Benefits from exercise may be accrued through improved physical well-being, reduced treatment-related side effects, better treatment adherence, better overall QoL, lower associated health care costs, and perhaps even longer survival.</p> <p>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.</p> <p>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.</p> <p>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.</p>




Prof Sandi Hayes
Principal Investigator

Current Clinical Trials

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OVARIAN


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.
Principal Investigator	Prof Linda Mileshtkin
Collaborations	University College London (UCL)-led international trial, ANZGOG lead group for Australia and New Zealand in collaboration with the NHMRC CTC
Funding	Cancer Australia UCL, U.K.
Study Milestones	Planned Sample Size: 110 (ANZ) 618 (Globally) Planned Number of Sites: 19 ANZ Accrual: 46 patients 18 sites
Contact	icon9@ctc.usyd.edu.au
Summary	<div><p>Prof Linda Mileshtkin Principal Investigator</p></div> <p>The goal of this international, investigator-initiated, randomised, placebo controlled, double blind Phase III trial is to improve outcomes for patients with recurrent ovarian cancer by investigating the addition of cediranib to olaparib maintenance therapy following completion of platinum-based chemotherapy for platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer.</p>

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OVARIAN

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.
Principal Investigator	Prof Clare Scott Assoc Prof Chee Lee (Co-Chair), Prof Michael Friedlander AM (Co-Chair)
Translational Chair	Prof Magdalena Plebanski
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC, RMIT and WEHI
Funding	AstraZeneca
Study Milestones	Planned Sample Size: 114 Planned Number of Sites: 15 Accrual: 44 patients 15 sites
Contact	solace2@ctc.usyd.edu.au
Summary	<div><p>Prof Clare Scott Principal Investigator</p></div> <p>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.</p>

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OVARIAN

Study	EMBRACE
Title	A Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient metastatic breast and relapsed ovarian cancer in patients without germline mutations in BRCA1 and BRCA2.
Principal Investigator	Dr Katrin Sjoquist
Collaborations	Initiated in Australia in collaboration with Breast Cancer Trials (BCT), ANZGOG, and the Genomic Cancer Clinical Trials Initiative (GCCTI)
Funding	Cancer Australia
Study Milestones	Planned Sample Size: 60 Planned Number of Sites: 11 Accrual: 10 patients 10 sites
Contact	EMBRACE@ctc.usyd.edu.au
Summary	<div><p>Dr Katrin Sjoquist Principal Investigator</p></div> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p>

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OVARIAN

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 stage high grade serous ovarian, fallopian tube and peritoneal cancers.
Principal Investigator	Assoc Prof Tarek Meniawy
Collaborations	Initiated in Australia by ANZGOG
Funding	AstraZeneca OASIS Initiative
Study Milestones	Planned Sample Size: 75 Planned Number of Sites: 10 Accrual: 63 patients 10 sites
Contact	trials@anzgog.org.au
Summary	<p>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.</p> <p>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.</p>



Assoc Prof Tarek Meniawy
Principal Investigator

Current Clinical Trials

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OVARIAN

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.
Principal Investigator	Prof Linda Mileschkin
Collaborations	National University Hospital, Singapore (NUHS)-led international trial, ANZGOG lead group for Australia and New Zealand
Funding	OASIS Initiative Baker Foundation Grant
Study Milestones	Planned Sample Size: 15 (ANZ) 36 (Globally) Planned Number of Sites: 7 ANZ Accrual: 0 patients 4 sites
Contact	trials@anzgog.org.au
Summary	<p>Vinorelbine is a chemotherapeutic agent that is currently used for treatment of lung and breast cancer. Recent research has identified four molecular sub-types of high grade serous ovarian cancer: C1, C2, C4 and C5. The C5 subgroup has been found to be relatively resistant to the platinum chemotherapy drugs typically used to treat ovarian cancer, with a poor prognosis compared with the other subgroups.</p> <p>In laboratory studies, vinorelbine has been shown to slow the growth of tumour 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 effect in patients with relapsed 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 tumour specimens from women enrolled on the trial may be used to predict the chance of benefiting from study treatment.</p>



Prof Linda Mileschkin
Principal Investigator

Current Clinical Trials

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OVARIAN

Study	STICs and STONEs
Title	A randomised phase II double-blind placebo-controlled trial of acetylsalicylic acid (Aspirin) for prevention of ovarian cancer in women with BRCA1 and BRCA2 mutations.
Principal Investigator	Prof Kelly-Anne Phillips
Collaborations	Canadian Cancer Trials Group (CCTG)-led international trial, ANZGOG lead group for Australia and New Zealand in collaboration with the NHMRC CTC
Funding	NHMRC Clinical Trial Centre Project Grant Support from Canadian Cancer Trials Group (CCTG)
Study Milestones	Planned Sample Size: 70 (ANZ) 414 (Globally) Planned Number of Sites: 6 ANZ Accrual: 1 patient 4 sites
Contact	stics@ctc.usyd.edu.au
Summary	<p>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 were not optimal.</p> <p>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.</p> <p>The study will provide a better understanding of how ovarian and fallopian tube cancers start and whether aspirin might be a useful prevention agent.</p>



Prof Kelly-Anne Phillips
Principal Investigator

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OVARIAN

Study	TIPS
Title	Testing Individual Interventions to Optimize Perioperative Care in Ovarian Cancer Surgery.
Principal Investigator	Assoc Prof Alison Brand
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	ASGO Grant ANZGOG Fund for New Research Grant
Study Milestones	Planned Sample Size: 60 Planned Number of Sites: 6 Accrual: 1 patient 4 sites
Contact	tips@ctc.usyd.edu.au
Summary	<p>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.</p> <p>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.</p> <p>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.</p>




Assoc Prof Alison Brand
Principal Investigator

Current Clinical Trials

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OVARIAN


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.
Principal Investigator	Dr Ali Freimund
Collaborations	Initiated in Australia by ANZGOG
Funding	BeiGene OASIS Initiative, Baker Foundation Grant Perpetual Philanthropic Grant
Study Milestones	Planned Sample Size: 40 (200 to be screened) Planned Number of Sites: 7 Accrual: 0 patients 5 sites
Contact	trials@anzgog.org.au
Summary	<div><p>Dr Ali Freimund Principal Investigator</p></div> <p>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 gene tests for patients with the hope to improve patient outcomes.</p>

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OVARIAN

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.
Principal Investigator	Dr George Au-Yeung
Collaborations	Initiated in Australia by ANZGOG
Funding	AstraZeneca
Study Milestones	Planned Sample Size: 64 (350 to be screened) Planned Number of Sites: 10 Accrual: 7 patients 3 sites
Contact	trials@anzgog.org.au
Summary	<div><p>Dr George Au-Yeung Principal Investigator</p></div> <p>IGNITE is a Phase II signal-seeking trial of adavosertib (AZD1775), an oral WEE1 kinase inhibitor, targeting recurrent platinum resistant high grade serous ovarian cancer with cyclin E1 over-expression with and without gene amplification. The trial opened to recruitment in January 2020, and due to open at 10 planned sites.</p>

Current Clinical Trials

TRIALS IN START UP as at June 30 2020


ENDOMETRIAL

Study	AtTEnd
Title	Phase III double-blind randomized placebo controlled trial of atezolizumab in combination with paclitaxel and carboplatin in women with advanced/recurrent endometrial cancer.
Principal Investigator	Dr Yoland Antill
Collaborations	Mario Negri Gynecology Oncology Group (MaNGO), ANZGOG lead group for Australia and New Zealand in collaboration with the NHMRC CTC
Funding	MaNGO
Study Milestones	Planned Sample Size: 80 (ANZ) 550 (Globally) Planned Number of Sites: 19 ANZ
Contact	attend@ctc.usyd.edu.au
<div><div><div><div><div><div></div></div></div><div><div><div></div><div></div></div></div><div><div><div></div><div></div></div></div><div><div><div></div></div></div></div></div></div> <div><div>Summary</div><div><div><div>Dr Yoland Antill</div><div>Principal Investigator</div></div></div></div>	<p>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.</p> <p>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.</p>

Current Clinical Trials

TRIALS IN START UP as at June 30 2020


OVARIAN/ENDOMETRIAL

Study	HyNOVA
Title	A randomised study comparing Hyperthermic and Normothermic intraperitoneal chemotherapy following interval cytoreductive surgery for stage III epithelial ovarian, fallopian tube and primary peritoneal cancer.
Principal Investigator	Assoc Prof Rhonda Farrell
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant
Study Milestones	Planned Sample Size: 80 Planned Number of Sites: 5
Contact	HyNOVA@ctc.usyd.edu.au
Summary	<div><p>Assoc Prof Rhonda Farrell Principal Investigator</p></div> <p>HyNOVA is a clinical trial comparing the effect of heated chemotherapy given into the abdominal cavity at a temperature of 42°C (HIPEC) to that given at body temperature of 37°C (NIPEC) at the time of surgery to women with advanced cancer of the ovary, fallopian tube or peritoneum. A recent study showed better survival in this group after treatment with HIPEC compared with no HIPEC. However, oncologists remain undecided about the potential benefit and harm of applying heat to the chemotherapy.</p>

Current Clinical Trials

TRIALS IN START UP as at June 30 2020


ENDOMETRIAL

Study	ADELE
Title	Adjuvant Tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high risk endometrial cancer.
Principal Investigator	Prof Linda Mileschkin
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant
Study Milestones	Planned Sample Size: 135 Planned Number of Sites: 23
Contact	ADELE@ctc.usyd.edu.au
Summary	<div><p>Prof Linda Mileschkin Principal Investigator</p></div> <p>This clinical trial seeks to improve outcomes for women with high-risk endometrial cancer, who have a significant risk of relapse after standard post-operative treatment with chemotherapy and radiotherapy. The trial will find out if relapse rates can be lowered by adding immunotherapy to current standard therapy. Women will be randomly assigned to receive the new treatment combination or existing standard treatment, then followed up to see if outcomes are improved and what side-effects occur.</p>

Current Clinical Trials

TRIALS IN START UP as at June 30 2020

OVARIAN/ENDOMETRIAL

Study	PARAGON-II
Title	Phase II basket study of an ARomatase inhibitor plus PI3KCA inhibitor or CDK4/6 inhibitor in women with hormone receptor positive recurrent/metastatic Gynaecological Neoplasms.
Principal Investigator	Assoc Prof Chee Khoon Lee Prof Michael Friedlander AM (Co-Chair)
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant
Study Milestones	Planned Sample Size: 182 Planned Number of Sites: 15
Contact	PARAGON2@ctc.usyd.edu.au
Summary	<div><p>Assoc Prof Chee Khoon Lee Principal Investigator</p></div> <p>PARAGON-II is a trial for women with gynaecological cancers whose tumours are potentially treatable with hormonal treatment. These patients must have cancers that have recurred or metastasised. For patients whose cancers have a genetic mutation called PIK3CA, they will be treated with letrozole hormonal treatment and alpelisib that targets PI3KCA. For those without PIK3CA mutation, these patients will be treated with letrozole and ribociclib, another new oral targeted treatment.</p>

Current Clinical Trials

TRIALS CLOSED TO RECRUITMENT as at June 30 2020

ENDOMETRIAL

Study	FeMMe
Title	A phase II randomised clinical trial of Mirena® ± metformin ± weight loss intervention in patients with early stage cancer of the endometrium.
Principal Investigator	Prof Andreas Obermair
Collaborations	Initiated in Australia in collaboration with the Queensland Centre for Gynaecological Cancer and ANZGOG
Funding	Lord Mayors Community Trust UQ Academic Title Holders Grant Cherish Women's Cancer Foundation RBWH Foundation Cancer Australia
Study Milestones	Accrual: 165 patients Planned Number of Sites: 15 sites (Closed to recruitment 22 Oct 2019)
Contact	vanessa.taylor3@health.qld.gov.au

OVARIAN

Study	MOCCA
Title	A multicentre phase II randomised trial of durvalumab (MEDI4736) versus physician's choice chemotherapy in recurrent ovarian clear cell adenocarcinomas.
Principal Investigator	Prof Michael Friedlander AM
Collaborations	National University Hospital, Singapore (NUHS)-led international trial, ANZGOG lead group for Australia and New Zealand
Funding	National University Hospital, Singapore (NUHS) OASIS Initiative
Study Milestones	Accrual: 9 patients 3 sites (Closed to recruitment 2 March 2020)
Contact	trials@anzgog.org.au

CERVICAL




Study	EXCISE
Title	Excisional treatment in women with cervical adenocarcinoma-in-situ (AIS): a prospective randomised controlled non-inferiority trial to compare AIS persistence/recurrence after loop electrosurgical excision procedure to cold knife cone biopsy.
Principal Investigator	Dr Paul Cohen
Collaborations	Initiated in Australia by St John of God Subiaco
Funding	ANZGOG Fund for New Research Grant
Study Milestones	Accrual: 40 patients 7 sites (Closed to recruitment 6 September 2019)
Contact	trials@anzgog.org.au



Improving life for
women through
cancer research

The Australia New Zealand Gynaecological Oncology Group (ANZGOG)
is the peak national gynaecological cancer research organisation.
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