



TRIALS NEWSLETTER

Summer 2010 Edition

Inside this Issue:

Message from Chair.....	1
Upcoming Events.....	1
Message from CTC Associate Program Manager	2
Meet one of the CTC Team.....	2
Message from the Executive Officer	3
ANZGOG Operations Team.....	3
ANZGOG Recruitment.....	4
Recruitment by ANZGOG Sites.....	5
PORTEC 3 Trial.....	6
SYMPTOM BENEFIT Trial.....	7
OVAR 16 Trial.....	8
ACCELERATED BEP Study.....	9
Pending Trials.....	10, 11
Studies in Follow Up Phase.....	12 - 15

Upcoming Events:

- **ANZGOG ASM 2010**
February 24 - 27, 2010; Noosa
(Visit www.anzgog.org.au for more information)
- **ANZGOG AGM 2010**
Thursday, February 25, 2010; Noosa
- **COSA ASM 2010**
November 9 - 11, 2010; Melbourne

Message from Chair

2010 will be a challenging year for ANZGOG as we get used to our new structure as an incorporated body and as we apply for continued core infrastructure funding on which our existence depends!

A number of key areas need to be successful to ensure ongoing support including improving patient accrual into trials, enhancing our community interaction, developing homegrown studies and ensuring excellent quality control.

We had well over a hundred patients accrued into the various studies in 2009. This year we anticipate a large increase due to Symptom Benefit and Paragon. We need better participation in PORTEC3 with 10 of our 17 sites not entering patients over the last 6 months. OVAR16 will probably stop recruiting in June and we need at least 50 patients randomised by then....31 to go!

Our community endeavours last year included the Noosa meeting, the Strategic Planning meeting and the Consumer and Community Committee Training Workshop held jointly with COSA.

As part of the Infrastructure Grant that ANZGOG currently holds from the Cancer Institute NSW, we now have \$10,000 per year available for the next two years to hold concept / protocol development workshops. Once a basic concept has been approved by the RAC for further development, these funds can be used to facilitate meetings to bring clinicians, researchers and statisticians together to develop the protocol more expediently.

Quality Assurance is critical to ensuring trial outcomes are what they purport to be. This year we will be reviewing our mechanisms for trial audit to ensure our data input is first class.

The Annual Meeting is soon upon us. This year we have a panoply of national and international stars to keep up the high standard of previous years. Do come along. There is something for everyone!

Professor Michael Quinn
ANZGOG Chair





NHMRC Clinical Trial Centre News

Message from CTC Associate Program Manager

Greetings from the team at the NHMRC Clinical Trials Centre. We hope you will find plenty of interest in this Summer '10 edition of the ANZGOG Trials newsletter! In this current issue you will find information about new and current trials, our regular column profiling a CTC staff member and other interesting information from the NHMRC Clinical Trials Centre.

The ANZGOG trials portfolio remains as dynamic as ever. On pages 4 & 5, you can see that one new trial opened to recruitment in August 2009 (OVAR16), and on December 18 the TRIPOD study closed to recruitment, having met (and slightly exceeded) the minimum target of 35 patients. It is great to see that two concepts previously presented at our Noosa Annual Scientific meeting are now about to develop into mature trials. These are OUTBACK (PI Linda Mileskin) and PARAGON (PI Michael Friedlander). You can read more about these trials inside.

Our relationship with the Gynaecological Cancer Intergroup (GCIG) continues to strengthen. Michael Quinn is Chair Elect of the GCIG taking over in October this year and at the last meeting in Belgrade, Serbia, I was elected as the Chair of the GCIG Harmonisation and Stats Committee. This gives us a great opportunity to learn from the experience of other groups and to find improved ways to collaborate and increase the efficiency with which we conduct our Intergroup studies.

ANZGOG's profile could hardly be higher on the international gynaecological oncology stage and this is largely due to the high regard in which we are held for the excellent standards we maintain in all aspects of trial conduct. It is without a doubt the efforts of the hard working staff at our participating centres that have enabled us to establish and maintain this reputation. We really appreciate your contributions, and remember that the team at the Clinical Trials Centre are here to help you keep up the great work.

Dr Julie Martyn
Associate Program Manager

Meet one of the CTC Trial Coordinators



In this issue, we are pleased to introduce Ilka Kolodziej. Ilka joined the Clinical Trials Centre in May 2008 to work as data manager on a large neonatal trial. Towards the end of 2008 she started working on ANZGOG studies, initially as trial coordinator for SCOTROC4 and soon after for OVAR16. In early 2010 she will be handing SCOTROC4 and OVAR16 over to her colleague Hannah Cahill and taking on OUTBACK and PORTEC-3. Ilka's background is in Applied Sciences. She has experience in various areas of health and medical research. In her spare time Ilka enjoys playing badminton and going to the movies.



NHMRC Clinical Trials Centre
Locked Bag 77
CAMPERDOWN NSW 1450



NHMRC CTC Team
T: +61 2 9562 5000
F: +61 2 9562 5094



ANZGOG Group News

Message from Executive Officer

We have started the new year moving full steam ahead! We are only 4 weeks away from the ANZGOG Annual Scientific Meeting 2010!!! On behalf of the ANZGOG Board, I would like to especially invite our new members and valued consumers to share with us a welcome drink on Wednesday, February 24th at 6:30pm at the Sheraton Resort in Noosa to kick off the ANZGOG ASM 2010. Please register for the conference and join in this excellent opportunity to mingle with colleagues, leading clinicians in the field of gynaecological oncology, researchers and distinguished guests!

The ASM 2010 Steering Committee would like to thank those who submitted Abstracts and New Trial Concepts for review and would like to heartily congratulate the successful applicants chosen to present at the conference. This year's Abstracts and Concepts include an interesting selection of research proposals and we look forward to these presentations.

On behalf of our members, I would like to sincerely thank Andreas Obermair, the Chair of the Conference Steering Committee and his fellow committee members including Michael Quinn, Michael Friedlander, Michelle Vaughan, Danny Rischin, Alison Brand, Belinda Egan and Kate Murphy for their time and dedication to ensuring a stimulating, social and educational conference. My deep appreciation goes out to the team at YRD for their organization and coordination of the conference once again this year and to our principal sponsor Schering-Plough.

I look forward to welcoming you all in Noosa!

Ayanthi Salgado
ANZGOG Executive Officer

The ANZGOG ASM 2010 February 24 - 27 Sheraton Resort & Spa, Noosa

To register and for Program details go to:

www.anzgog.org.au

Your Operations Team

Ayanthi Salgado

ANZGOG Executive Officer
asalgado@anzgog.org.au
+61 2 9562 5054

Heshani Nesfield

Administrative Officer - Communications
hnesfield@anzgog.org.au
+61 2 9562 5363

Dianne Merrick

Administrative Officer - Fundraising
dmerrick@anzgog.org.au
+61 2 9562 5082

Joy Howe

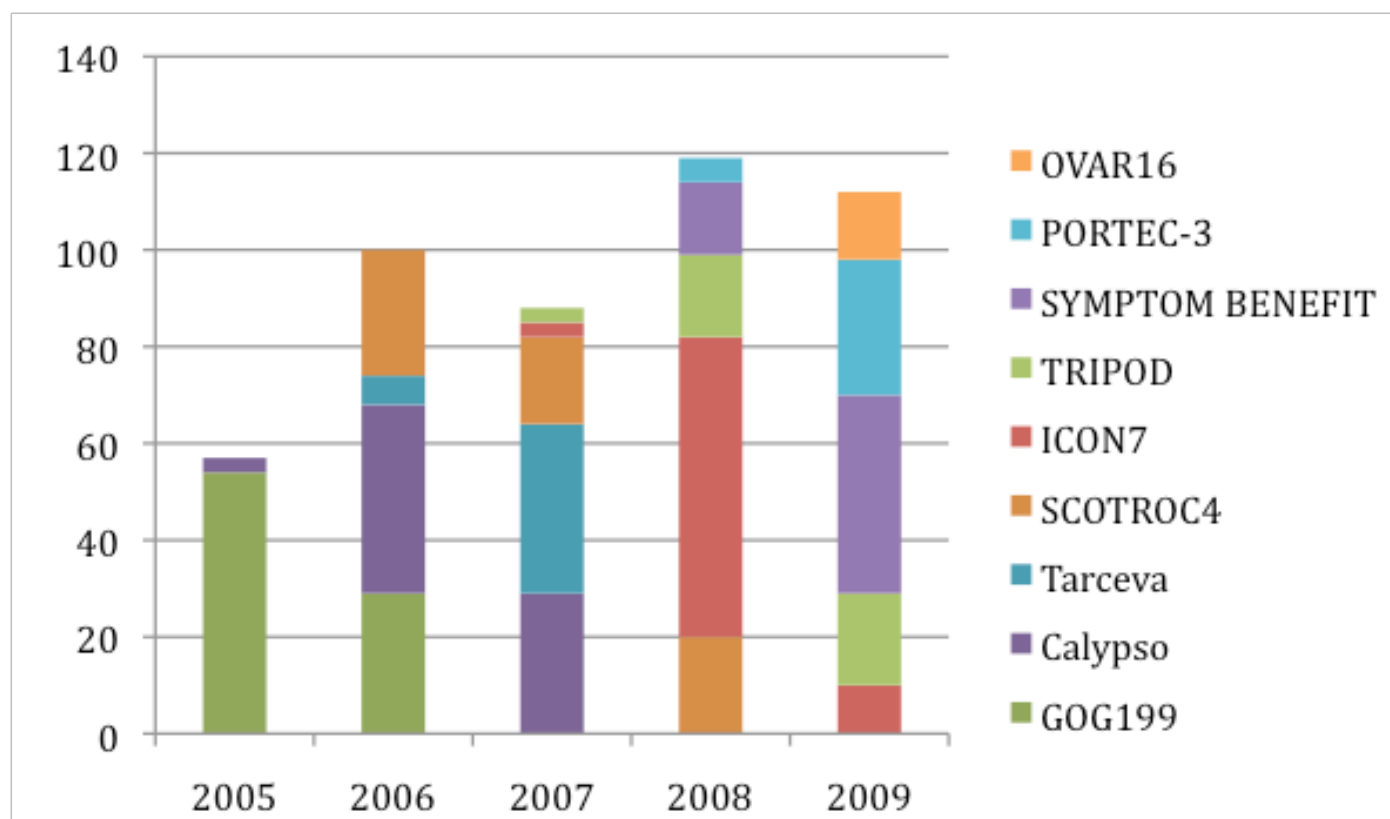
Bookkeeper
jhowe@anzgog.org.au



Dianne, Heshani, Ayanthi and Joy

ANZGOG Recruitment

We recruited a total of 112 patients in 2009. This graph shows our annual recruitment over the last 5 years and shows a pleasing upward trend as our trials portfolio has continued to strengthen.

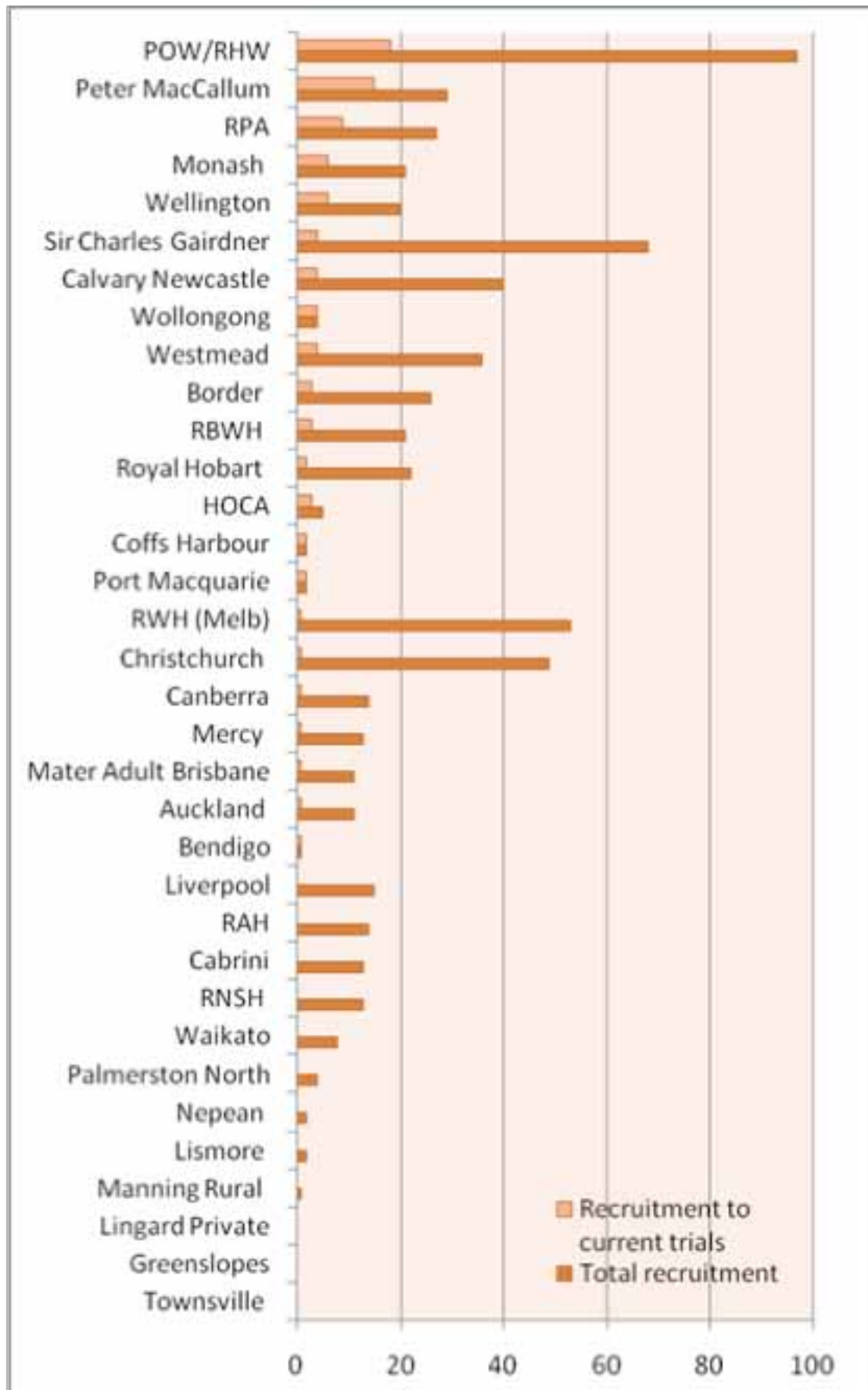


2010 should be a very busy year with three new trials expected to open and Symptom Benefit due to go international; OVAR 16 however will close around June.

When we look at the numbers of patients by site, it is clear that it continues to be a fairly small number of sites that are making a large contribution to our total patient numbers. Our highest recruiting site in 2009 was the Princess Margaret Hospital in Canada which put 17 patients onto the Symptom Benefit study. Of special note however, Michael Friedlander and the team at Prince of Wales/Royal Hospital for Women are just 6 patients away from the very impressive feat of putting 100 patients on to ANZGOG studies (and yes, we will bring you cake when you reach that milestone!)

We now have a pool of 47 institutions that have opened at least one ANZGOG study since 2002. We are very pleased that some new centres have come on board during 2009 but a few that have been valuable contributors in the past are not so active now. Only 22 ANZ sites have patients enrolled on our currently recruiting trials. The remaining sites either have the trials open but have not recruited any patients, or they have not elected to participate in the trials we have on offer. The reasons behind this are no doubt many and complex but we would like to do whatever we can to get active participation from as many centres as possible and would value your feedback as to how we can work towards this aim.

Recruitment by ANZGOG Sites



PORTEC 3

Randomized Phase III Trial, Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma.

Site	PI	Status	Recruitment
Auckland Hospital	Dr Susan Brooks	Active	1
Christchurch Hospital	Dr Michelle Vaughan	Active	1
Mater Adult Brisbane	Dr Paul Mainwaring/Dr Jonathon Ramsay	Active	1
Monash Medical Centre/ Peter MacCallum Cancer Centre (Moorabbin)	Dr Pearly Khaw/Dr Geraldine Goss	Active	6
Palmerston North Hospital	Dr Claire Hardie	Active	0
Peter MacCallum Cancer Centre	Dr Linda Mileschkin (PI)	Active	12
Prince of Wales/Royal Women's Hospital	Prof Michael Friedlander	Active	0
Royal Brisbane and Women's Hospital	Dr Robyn Cheuk	Active	1
Royal Hobart Hospital	Dr Penny Blomfield	Active	0
Royal North Shore Hospital	Dr Gillian Lamoury	Active	0
Royal Prince Alfred Hospital	Prof Chris Milross	Active	0
Waikato Hospital	Dr Marion Kuper	Active	0
Wellington Hospital	Dr Carol Johnson	Active	6
Westmead Hospital	Dr Gerard Wain	Active	3
Woollongong – Illawarra Cancer Centre	Dr Amanda Glasgow/ Kerwyn Foo	Active	2
Calvary Mater Newcastle	Dr Anne Capp	HREC approved	-
Launceston General Hospital	Dr David Byram	Pending	-
Sir Charles Gairdner	Dr Martin Buck	Pending	-
Townsville Hospital	Dr Susan Hewitt	Pending	-
Total			33

Current Status

- 15 ANZGOG centres have been activated.
- A total of 33 ANZ patients have been recruited.
- A total of 133 patients have been recruited internationally to date.
- The preferences sub-study has commenced at most sites. Mini-initiations can be arranged for each site upon request. Martin Stockler and Prunella Blinman are available to discuss the sub-study with investigators.

Updates

- There is an upcoming protocol amendment which incorporates FIGO 2008 staging and provides more specifics for dose reduction of adjuvant chemotherapy. Further information will be sent to sites about this in the coming months.
- The CRFs have recently been updated and emailed to all sites. Please use CRFs dated 26 October 2009 from now on. Thank you.

Trial Coordinator

Sarah Chinchin
schinchin@ctc.usyd.edu.au
Phone: 02 9562 5066
portec3@ctc.usyd.edu.au

SYMPTOM BENEFIT

Does Palliative Chemotherapy Improve Symptoms in Women with Recurrent Ovarian Cancer?

The Symptom Benefit study is a collaboration between ANZGOG, PoCoG and GCIG members.

Site	Date Activated	Recruitment
Illawarra Cancer Centre	12/06/08	2
Prince of Wales Hospital	26/09/08	15
Royal Prince Alfred Hospital	08/05/08	9
Royal North Shore Hospital	29/10/08	0
Princess Margaret Hospital – Canada	16/07/08	18
Juravinski Cancer Centre – Canada	12/06/08	6
Westmead Hospital	30/04/09	2
Border Medical Oncology	16/06/09	3
Lingard Private Hospital	06/07/09	0
Canberra Hospital	30/07/09	1
Calvary Mater Newcastle	24/08/09	0
NCCI - Coffs Harbour	18/09/09	2
Greenslopes Private Hospital	24/08/09	0
NCCI - Port Macquarie	30/09/09	2
Peter MacCallum	23/11/09	2
Bendigo	09/12/09	1
Total		63

Current Status

- Symptom Benefit opened in May 2008 and we now have 16 sites open to recruitment and a total of 60 patients thus far.
- Development of Stage 2 is well underway and a protocol revision is forthcoming.
- There will be an Investigator Meeting for Stage 2 in Noosa on Friday, February 26th from 11:00-11:45am.
- The Symptom Benefit study is a collaboration between ANZGOG, PoCoG and GCIG members.

Trial Coordinator

Kim Gillies
kgillies@ctc.usyd.edu.au
Phone: 02 9562 5032
symptombenefit@ctc.usyd.edu.au

OVAR 16

A Phase III Study to Evaluate the Efficacy and Safety of 12 months of maintenance therapy with Pazopanip versus Placebo in Women who have not progressed after First Line Chemotherapy for Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancers.

Site	PI	Date Activated	Recruitment
Prince of Wales Hospital	Prof Michael Friedlander	14-Aug-09	3
Border Medical Oncology	Dr Christopher Steer	17-Aug-09	0
Royal Brisbane and Women's Hospital	Dr Jeffrey Goh	17-Aug-09	2
Calvary Mater Newcastle	Dr Tony Bonaventura	18-Aug-09	4
Royal Hobart Hospital	Dr Rob McIntosh	25-Aug-09	2
Mercy Hospital for Women	A/Prof Danny Rischin	03-Sep-09	1
Royal Prince Alfred Hospital	A/Prof Philip Beale	05-Oct-09	1
Royal Women's Hospital, Melbourne	Prof Michael Quinn	28-Sep-09	1
HOCA	A/Prof Paul Vasey	09-Oct-09	3
Liverpool Hospital	Dr Amanda Goldrick	16-Nov-09	0
Cabrini Hospital	A/Prof Gary Richardson	25-Nov-09	0
Sir Charles Gairdner Hospital	Dr Martin Buck	27-Nov-09	4
Royal Adelaide Hospital	A/Prof Margaret Davy	04-Nov-09	0
Total			21

Current Status

- All 13 Australian centres now open to recruitment.
- 17/50 patients recruited (34%) to date.

Updates

- Global recruitment has been very fast. The trial will close sooner than originally planned. The current predicted close of recruitment is June 2010.
- Australian recruitment needs to pick up in order to meet our recruitment target.

FAQ

Q: If I have a question, should I contact ANZGOG or GSK?

A: Please direct all eligibility/scientific or clinical queries to ANZGOG. If your question relates to study processes such as data collection, assessment schedules, study drug, monitoring or adverse events please contact GSK.

Trial Coordinator

Hannah Cahill
hannah.cahill@ctc.usyd.edu.au
Phone: 02 9562 5331
ovar16@ctc.usyd.edu.au

ACCELERATED BEP

A feasibility study of accelerated BEP as first line chemotherapy for advanced germ cell tumours. An Intergroup study with ANZUP as the lead group.

Site	PI	Status	Recruitment
Royal Adelaide Hospital	Dr Nimit Singhal	Active	4
Flinders Medical Centre	Dr Craig Underhill	Active	0
Royal Melbourne Hospital	Prof. Mark Rosenthal	Active	6
Western Hospital	Dr. Shirley Wong	Active	4
Peter MacCallum	A/Prof. Guy Toner	Active	0
Border Medical Oncology	Dr. Craig Underhill	Active	0
St Vincent's Hospital, Melbourne	Dr. Ivon Burns	Active	0
Concord Hospital	A/Prof. Martin Stockler	Active	3
Royal Prince Alfred	A/Prof. Martin Stockler	Active	2
Prince of Wales	Prof. Michael Friedlander	Active	2
Westmead Hospital	A/Prof. Howard Gurney	Active	5
Nepean Cancer Care	Dr. Brian Orr	Active	0
Wesley Hospital	Dr. Paul Vasey	Active	3
Princess Alexandra Hospital	A/Prof. Damien Thomson	Active	4
Total			33

Current Status

- 14 ANZGCTG/ANZGOG centres have been activated
- 33 Australian patients have been recruited across 9 of the active sites.

Updates

- Initial target of 25 patients achieved in July 2009, and as permitted in the protocol, target extended to 45 patients to obtain more reliable data about toxicity and efficacy.
- Formal stage 2 analysis of the first 30 patients has been performed by Mark Chatfield (Trial statistician) and Val GebSKI (CTC statistician). Dr Peter Grimison to present analysis at ASCO GU in February 2010 in San Francisco.

Trial Coordinator

Angus McDonald
angus.mcdonald@ctc.usyd.edu.au
Phone: 02 9562 5310

Pending Trials:

OUTBACK

A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone.

The OUTBACK trial is currently under development. Dr Linda Mileschkin from Melbourne will be the Principal Investigator. OUTBACK will be an international, multi-centre trial led by ANZGOG.

This trial will be for women with stage IB2-IVa cervical cancer suitable for primary treatment with chemoradiation. It will determine if the addition of adjuvant chemotherapy to standard cisplatin-based chemoradiation improves progression-free survival. Overall the trial will recruit approximately 780 participants. It is anticipated that OUTBACK will open to recruitment in mid-2010.

Current Status

- Trial is in the start up phase
- Protocol, PDCF and CRFs are being developed.
- ANZ Site feasibility surveys have been sent out and responses are being collated.
- A grant application is being prepared for submission to the NHMRC/Cancer Australia.
- There is discussion with other GCIG members about global participation.
- Hospira have agreed to provide Paclitaxel for patients in Australia.
- **There will be an Investigator Meeting for OUTBACK in Noosa on Thursday, February 25th from 7:00-7:50am.**

Trial Coordinator

Ilka Kolodziej
ilka.kolodziej@ctc.usyd.edu.au
Phone: 02 9562 5079
outback@ctc.usyd.edu.au

PARAGON

Phase 2 study of anastrozole in women with potentially hormone sensitive recurrent/metastatic Gynaecological Neoplasms.

The aim of this study is to assess the activity of anastrozole, an aromatase inhibitor, in women with Estrogen receptor and/or progesterone receptor positive (ER/PR+ve) and therefore potentially hormone responsive recurrent or metastatic gynaecological cancers. Professor Michael Friedlander is the Principal Investigator.

The study will include selected patients with epithelial ovarian cancer, endometrial cancers, miscellaneous sarcomas and sex cord stromal tumours of the ovary. The primary endpoints will be objective response rate, clinical benefit, quality of life, toxicity and duration of response.

Current Status

- This study is currently in the protocol development stage.
- The study has received co-funding from Cancer Australia and the National Centre for Gynaecological Cancer.
- A number of GCIG groups have expressed an interest in participating in this trial.
- **There will be an Investigator Meeting for PARAGON in Noosa on Friday, February 26th from 7:45-8:45am.**

Trial Coordinator

Kim Gillies
kgillies@ctc.usyd.edu.au
Phone: 02 9562 5032
paragon@ctc.usyd.edu.au

Pending Trials:

ICON 6

A randomised trial of concurrent cediranib (with platinum-based chemotherapy) and maintenance cediranib in women with platinum-sensitive relapsed ovarian cancer.

There is currently an amendment to the protocol before ethics in the UK and this is expected to be approved late January 2010. This amendment is a request to broaden the standard therapy to include gemcitabine. Once this amendment is approved we will submit the amendment to NSW Cancer Institute and then circulate to sites.

Although we were originally to take part in Stage 1, this has virtually completed in the UK so Australia will enter Stage 2 once we have the amended protocol. Five sites were already in the process of setting up for Stage 1 and they will be joined by additional sites once the amendment is approved. A feasibility study was done again in August 2009 with a view to sites entering Stage 2 with a protocol allowing for an expanded standard treatment. Feasibility assessments carried out at the end of last year yielded positive responses from 23 sites with a significant increase in the estimated number of patients if the expanded standard treatment was approved.

Current Status:

- We are preparing a grant application for NHMRC/ Cancer Australia Project Grant funding, to supplement the funding available from the MRC. Applications close on March 17, and if successful, funding will be available in early 2011.
- **There will be an Investigator Meeting during the Noosa Annual Scientific Meeting to provide further updates on ICON6. This will be on Thursday, February 25 from 4:30 - 5:30pm.**

Trial Coordinator

Kerri Carlton
kerri.carlton@ctc.usyd.edu.au
Phone: 02 9562 5067
icon6@ctc.usyd.edu.au



Studies in the Follow Up Phase: TRIPOD

A Single Arm Phase II Trial of Intraperitoneal Chemotherapy with Paclitaxel and Cisplatin after Optimal Debulking Surgery for Ovarian and Related Cancers.

The TRIPOD trial was closed to recruitment on 18th December 2009. The total number of patients recruited was 39, meeting the study target of 35 – 100 patients. There are still 3 patients currently receiving study treatment and 35 patients are in the follow-up phase. The number of deceased patients is 1.

A final recruitment breakdown by site is shown in the following table:

Site	No. of Patients
Mater Adult Hospital Brisbane	10
Prince of Wales Hospital	4
Royal Adelaide Hospital	0
Royal Hobart Hospital	4
Royal Women's Hospital	2
Sir Charles Gairdner Hospital	1
Mercy Hospital	4
Border Medical Oncology	0
Westmead Hospital	2
Royal North Shore Hospital	2
Royal Prince Alfred Hospital	1
Flinders Medical Centre	4
Christchurch Hospital	4
Royal Brisbane & Women's Hospital	1
TOTAL	39

Having met a major study milestone, we would like to congratulate and thank everyone involved in the study for their great work so far, including all site data managers, trial coordinators and investigators. The huge effort made by all is very much appreciated by everybody here at the Clinical Trials Centre and ANZGOG.

The next stage of the study will take place during the middle of the year, with data cleaning and statistical analysis anticipated to commence when the last patient comes off study treatment in June 2010. An abstract submission is then expected for the end of the year, around October/November. Follow-up will be ongoing, with Quality of Life and Disease & Patient Status Data being collected for two years after end of treatment or until disease progression occurs. This should take us into 2012.

On a personal note, I will be leaving the CTC in mid-January and would like to take this opportunity to say farewell and thank everybody I have had the pleasure of working with. Details of the new TRIPOD Trial Coordinator will follow in due course.

Julia Messer
TRIPOD Trial Coordinator

Trial Coordinator
Appointment to be confirmed
tripod@ctc.usyd.edu.au

ICON 7

A randomised (1:1 ratio), 2 arm, multi-centre, GCIIG open-label phase III trial designed to evaluate the safety and efficacy of adding bevacizumab, a humanised monoclonal antibody against Vascular Endothelial Growth Factor (VEGF), to standard chemotherapy with carboplatin and Paclitaxel.

Site	Recruitment
Border Medical Oncology	6
Box Hill Hospital	2
Liverpool Hospital	0
Mater Adult Brisbane	0
Mercy Hospital for Women	2
Calvary Mater Newcastle	2
Prince of Wales Hospital	8
Royal Adelaide Hospital	2
Royal Brisbane & Women's Hospital	2
Royal Hobart Hospital	7
Royal North Shore Hospital	3
Royal Prince Alfred Hospital	3
The Women's Hospital	13
Sir Charles Gairdner Hospital	7
Westmead Hospital	0
Wesley Medical Centre	2
Lismore Base Hospital	1
Cabrini	1
Canberra Hospital	3
Christchurch	7
Dunedin	2
Wellington	3
TOTAL	76

Current Status

- ICON7 closed to recruitment in February 2009 after meeting the international recruitment target of 1528.
- ANZGOG sites recruited 76 patients (64 in Australia and 12 in New Zealand).
- Progression Free Survival analysis is being prepared with the data cut-off date set for 28th February 2010. The MRC have advised that the communication of results to investigators will occur later in the year.
- Follow-up and site monitoring continues.

Trial Coordinator

Kim Gillies
kgillies@ctc.usyd.edu.au
Phone: 02 9562 5032
icon7@ctc.usyd.edu.au

CALYPSO

A Multi-National, Randomised, Phase III, GCIG Intergroup Study Comparing Pegylated Liposomal Doxorubicin (CAELYX®) and Carboplatin vs. Paclitaxel and Carboplatin in Patients with Epithelial Ovarian Cancer in Late Relapse (>6 months).

It has been an exciting year for Calypso with the statistical analyses giving rise to a number of presentations. The Progression Free Survival results were presented by Eric Pujade-Lauraine at ASCO in May 2009, by Mark Haywood (NCIC) at ESGO in Belgrade in October 2009 and at ESMO in Berlin by Paul Vasey (ANZGOG) in September 2009. There are four further abstracts being submitted for ASCO 2010 including two sub-studies lead by ANZGOG and the CTC. The results being presented are considered significant and could have the effect of changing the standard treatment for relapsed ovarian cancer.

The ongoing analysis has meant that France has been up to date with data entry and queries and we are grateful for all sites dealing with their queries promptly. This has resulted in the lowest number of queries ever. The central TMF in France was also brought up to date in 2009 and a great deal of time was spent getting all the necessary paperwork to them to complete this.

Current Status

- 47 patients are deceased.
- 21 patients in follow up, 3 patients lost to follow up.
- Final monitoring visits are now being planned and patient monitoring should be finalized this year.

Trial Coordinator

Kerri Carlton
kerri.carlton@ctc.usyd.edu.au
Phone: 02 9562 5067
calypso@ctc.usyd.edu.au

EORTC 55041 TARCEVA

A randomised, multicentre, phase III study of Erlotinib versus observation in patients with no evidence of disease progression after first line, platinum-based chemotherapy for high-risk Stage I and Stage II-IV ovarian epithelial, primary peritoneal, or fallopian tube cancer.

Current Status

- We currently have 36 patients in follow up for the EORTC 55041 Tarceva study, with 6 patients deceased.
- All patients have completed the active study treatment. Many thanks to all of our sites for their diligence in maintaining great follow up stats. Overdue forms and queries are always attended to promptly.

Updates

- We would like to remind sites that the clinical cut-off date is expected by end of 2010. Database lock is foreseen 3-4 months prior, but we will keep you up to date with information as it comes to hand.
- We will be contacting sites shortly in relation to the shipping of translational research samples.

Clinical Trial Assistant

Hani Adhami
hadhami@ctc.usyd.edu.au
Phone: 02 9562 5085
tarceva@ctc.usyd.edu.au

Project Manager

Julie Martyn
julie.martyn@ctc.usyd.edu.au
02 9562 5092
tarceva@ctc.usyd.edu.au

SCOTROC 4

A Prospective, Multicentre, Randomised Trial of Carboplatin Flat Dosing vs. Inpatient Dose Escalation as First Line Chemotherapy of Ovarian, Fallopian Tube and Primary Peritoneal Cancers.

Current Status

- SCOTROC-4 closed to recruitment in January 2009.
- ANZGOG recruited 64 patients. Currently there are 37 pts in follow up, 24 pts deceased and 3 patients have withdrawn.
- SCOTROC-4 Abstract was selected for ASCO 2009 Publication.
- The Data Monitoring Committee has found no evidence of benefit for intra-patient dose escalation of carboplatin. A separate analysis of tissue samples, aimed at elucidating mechanisms of (single agent) carboplatin resistance is ongoing.

Trial Coordinator

Hannah Cahill
hannah.cahill@ctc.usyd.edu.au
Phone: 02 9562 5331
scotroc4@ctc.usyd.edu.au

Hannah Cahill is the new Trial Coordinator for SCOTROC-4. She has taken over from Ilka and works at the CTC Thursdays and Fridays 8-4pm. Please don't hesitate to contact her for assistance.

SCOTROC-4 Follow-up FAQs

Q: Patient visit schedule after progression?

A: Patients continue to follow the diary after progression. If not seen the Follow-Up Form first question is completed as "2" and the second question as "1" (not seen will be followed-up future date). Patients are followed up until they pass away.

Q: Data Queries

A: Data queries from SGCTG are sent to sites via email. Please ensure to submit the Data Query responses within 2 weeks of receipt.

Site Payments

- Site payments are due this month for patients on follow up.
- An invoice will be sent to sites soon.

GOG 182

- The GOG182 study opened to recruitment in 2002 and closed in September 2004, ANZGOG sites recruited 183 patients across 26 sites. Patients remain in follow-up and are followed up for life.

GOG 199

- This study opened to recruitment in 2004 and closed in November 2006, ANZGOG recruited 83 patients across 4 sites. Patients remain in follow-up and samples are regularly shipped to the GOG.

Trial Coordinator

Kim Gillies
kgillies@ctc.usyd.edu.au
Phone: 02 9562 5032
gog182@ctc.usyd.edu.au
gog199@ctc.usyd.edu.au