



# Trial News

Spring Edition

September 2008



## Editorial

Welcome to the Spring 2008 Edition of the ANZGOG Trials Newsletter.

The last six months have been busy ones for the Trials team at the ANZGOG Coordinating Centre, and there have been a number of notable highlights throughout this period.

Firstly, in June we recruited our 500<sup>th</sup> patient. It was a patient recruited to the TRIPOD study at Royal Hobart Hospital that enabled us to achieve this very significant milestone. As always we are tremendously grateful to our trial participants. It goes without saying that we couldn't run our studies without them.

In July, Symptom Benefit opened to recruitment at Royal Prince Alfred Hospital, closely followed by the Juravinski Cancer Centre in Ontario, Canada. Symptom Benefit is the first international GCIG study in which ANZGOG had taken the lead role. PORTEC-3 also opened to recruitment in July, in both Wellington and Christchurch, with Wollongong the first Australian site to open, in August. We look forward to recruiting our first patient to this trial soon.

The last few months have highlighted some new challenges as well. In particular the transition to central ethics approval in NSW seems to have led to a more complex research governance environment at some sites, resulting in delays in trial activations. The Trials team at the ANZGOG Coordinating Centre are keen to help, please contact us if we can be of assistance.

Recruitment remains a not-so-new challenge. Fewer than half of our sites have recruited patients to our currently open studies. Just six sites have contributed almost 60% of the patients to these studies. We hope that you will find our screening pads and compendiums useful, and that these will aid you in thinking about ANZGOG trials that may be suitable for your patients.

Thanks to you all for your great efforts in both our current studies and those which are closed to recruitment. With our new studies gaining momentum, and further exciting trial prospects in the pipeline, we are looking forward to a productive time ahead.

Finally I'd like to say on behalf of the ANZGOG Coordinating Centre team what a privilege and a pleasure it has been to work with Michael Friedlander in his role as Chair of ANZGOG. His tireless dedication to ANZGOG has been an inspiration. Michael Quinn has likewise been a fantastic advocate for ANZGOG and we look forward to working more closely with him in the future as he takes over as the new Chair of the group.

Julie Martyn  
ANZGOG Assoc Program Manager

NHMRC Clinical Trials Centre  
Locked Bag 77  
Camperdown NSW 1450

Tel: (02) +61 2 9562 5000  
Fax: (02) +61 2 9562 5094  
Email: [enquiry@anzgog.org.au](mailto:enquiry@anzgog.org.au)

### Contents

Editorial.....	Page 1
Message from the Chair.....	Page 2
Contacts.....	Page 3
One of the team.....	Page 4
ANZGOG/ASGO ASM.....	Page 4
Recruitment.....	Page 5
PORTEC-3.....	Page 6,7
Symptom Benefit.....	Page 8
TRIPOD.....	Page 9
ICON 7.....	Page 10
SCOTROC4.....	Page 11
CALYPSO/Accelerated BEP.....	Page 12
EORTC Tarceva.....	Page 13
GOG182/199.....	Page 14

## Message from the chair

It is with great pride in what has been achieved over the last decade that I contribute to my final newsletter as the chair of ANZGOG. It seems fitting that I take the opportunity to briefly reflect on the past as well as on the challenges ahead.

In 1999, a small group of gynaecologic, medical and radiation oncologists unanimously agreed that we needed to establish a gynaecologic trials group in Australia and New Zealand. I was charged with the responsibility of moving this forward and this has consumed a large amount of my time and attention since then. There was no funding available for collaborative trials groups and despite a lot of effort to secure funds in Australia it was clear that this would not be forthcoming. There was little appreciation of the importance of clinical trials within the health bureaucracy or funding bodies and we recognised we needed to obtain funding from outside Australia if we were to have any chance of success. It is amazing to see how this has changed in just 10 years with funds that have become available from Cancer Australia for new trial groups. I approached the US GOG regarding membership and after discussion with them and with a lot of help from Ted Trimble of CTEP, we decided that it would be in our best interest if we joined the GOG. They generously offered us start up funds and were genuinely interested in opening up the GOG to international groups. In order to meet the requirements of the GOG, I became the Principal Investigator for ANZ and we started the complex process of signing up all other investigators as affiliates to comply with the rules and regulatory requirements of the GOG. Haryana Dhillon was at the NHMRC Clinical Trials Centre; she worked tirelessly to make this happen and she deserves a lot of the credit for the early success of the group. Our first trial was GOG 182, a complex 5 arm randomised trial which we performed very well and this gave us the confidence to move forward and expand. We received a lot of help from the NHMRC Clinical Trials Centre and too many people to mention individually by name have worked very hard to make ANZGOG the success that it has become.

Over this period we also forged strong links with many groups around the world and were one of the founder groups involved in establishing the Gynaecological Cancer Inter-Group (GCIG). It is now widely accepted and acknowledged that we all need to work together and this has energised all the Groups who are now eagerly and effectively collaborating. There are now 21 member groups of the GCIG and the list of groups wanting to join is growing. I am very confident that this will rapidly lead to improvements in the management of women with gynaecological cancers throughout the world.

We have been successful in securing funds from the Cancer Institute NSW as well as Cancer Australia which have been essential for infrastructure support. However, we needed to raise funds for all our trials and this has largely been through grants. Fortunately we have been successful with many of our grant applications. We have applied for a number of large grants this year and the success of these are important to underpin the group and allow us to move forward.

We are very fortunate in having Julie Martyn and her team at the CTC who are responsible for the day to day running of ANZGOG and I would like to publicly acknowledge all of them and thank them for their hard work. There are so many others to acknowledge. We have a strong and committed Executive and Research Advisory Committee as well as a very active Study Coordinators Committee and Audit Committee. I am also delighted that Karen Livingstone has taken on the chair of the Consumer and Community subcommittee and she is forging ahead with ambitious plans.

There are many challenges ahead and secure funding is always going to be an issue until more long term funds are made available not only for infrastructure but also for trial support. We also need to consider incorporation which I think is now essential and we are actively considering the process. We need to increase the profile of ANZGOG in the community and become more involved in educating the public about clinical trials through open forums as well as via our website. However, the success of the group is totally dependent on you and all our members and the commitment to clinical trials. We need to individually and collectively reflect on this and ensure that we give our patients the opportunity to participate in our studies. We all know that clinical trials can be time consuming and expensive, but they are arguably the best and most efficient way to change the standard of care and improve outcomes.

I want to thank you all for giving me the opportunity to Chair ANZGOG through its development and formative years. I would like to continue to be closely involved with the group and hope to be able to contribute to the further growth and success of the group. I wish Michael Quinn, who is a close friend and colleague all the best. I know that under his leadership ANZGOG will flourish.

We will meet the day before COSA on Monday November 17 for our trials meeting and I would remind you that we have a very good gynaecological oncology program on the first day of COSA. Jonathan Lederman is our ANZGOG visitor this year and I hope that many of you will attend both the trials meeting and COSA.

Michael Friedlander



## Your ANZGOG team

### ANZGOG A/Program Manager

Julie Martyn  
Email: [jmartyn@ctc.usyd.edu.au](mailto:jmartyn@ctc.usyd.edu.au)  
Phone: (02) 9562 5092

### CALYPSO

Trial Coordinator: Kerri Carlton  
Email: [kcarlton@ctc.usyd.edu.au](mailto:kcarlton@ctc.usyd.edu.au)  
Phone: (02) 9562 5067

### ICON-7, GOG182 & 199, TRIPOD and SYMPTOM BENEFIT

Trial Coordinator: Kim Gillies  
Email: [kgillies@ctc.usyd.edu.au](mailto:kgillies@ctc.usyd.edu.au)  
Phone: (02) 9562 5085

### Clinical Trials Assistant

Mausam Doctor  
Email: [mdoctor@ctc.usyd.edu.au](mailto:mdoctor@ctc.usyd.edu.au)  
Phone: (02) 9562 5085

### ANZGOG Operations Manager

Ayanthi Salgado  
Email: [asalgado@ctc.usyd.edu.au](mailto:asalgado@ctc.usyd.edu.au)  
Phone: (02) 9562 5054

### SCOTROC4

Trial Coordinator: Raymond Tangunan  
Email: [rtanganan@ctc.usyd.edu.au](mailto:rtanganan@ctc.usyd.edu.au)  
Phone: (02) 9562 5044

### TARCEVA

Clinical Trial Assistant: Mausam Doctor  
Email: [mdoctor@ctc.usyd.edu.au](mailto:mdoctor@ctc.usyd.edu.au)  
Phone: (02) 9562 5032

### PORTEC-3

Trial Coordinator: Sarah Chinchin  
Email: [schinchin@ctc.usyd.edu.au](mailto:schinchin@ctc.usyd.edu.au)  
Phone: (02) 9562 5066

### ANZGOG Administrative Officer

Heshani Nesfield  
Email: [hnesfield@ctc.usyd.edu.au](mailto:hnesfield@ctc.usyd.edu.au)  
Phone: (02) 9562 5363

**NEWS FLASH!**

The NHMRC Clinical Trials Centre is moving to NEW premises

**After 19th of September 2008:**

**POSTAL ADDRESS:** Will remain UNCHANGED.  
Please continue to send all correspondence to:  
ANZGOG Coordinating Centre  
NHMRC Clinical Trials Centre  
Locked Bag 77  
Camperdown NSW 1450.

**TELEPHONE/FAX NUMBERS:**  
All telephone/fax numbers will remain UNCHANGED.

### OUR NEW STREET ADDRESSES:

#### ANZGOG OPERATIONS STAFF

ANZGOG Operations Office  
Medical Foundation Building  
92-94 Parramatta Road  
Camperdown NSW 2050

#### CLINICAL TRIALS OFFICE

Actual address and date of relocation to be confirmed—estimated Nov 2008



## One of the Team....

In order for you to get to know us better, we would like to take the opportunity in every ANZGOG Trials Newsletter, to share with you a short profile of one of the team. We would like to initiate this with a profile of our newest member—Sarah Chinchin.



Sarah started at the CTC in 2005 after completing a BSc and travelling. Sarah has worked as a clinical trials assistant, data manager and monitor on a venous thrombosis study at CTC and is delighted to join the ANZGOG team as the PORTEC-3 Trial Coordinator. Sarah is currently completing a Master of Public Health at The University of Sydney. Interests include movies, travel and snowboarding.

TIME TO REGISTER!

## ANZGOG/ASGO Annual Scientific Meeting 2009

Applications for Study Coordinators and consumer/community representatives travel scholarships will be available on the website and emailed directly to you soon. Please ensure you complete and send the application form in as soon as possible. Once again, we will make our best effort to sponsor fully or partially, as many Study Coordinators as we can depending on funds available. We will notify you as soon as a decision has been made on your application.

As there have been changes to airline scheduling to the Sunshine Coast, we strongly urge you to make travel arrangements as soon as you receive confirmation of your registration.

We have a fun and educational program planned, as well as plenty of networking opportunities catered for. Send in your applications ASAP so you don't miss out!

The ANZGOG website ([www.anzgog.org.au](http://www.anzgog.org.au)) is a useful source of both group and trial specific information. Please log in regularly to check for current information.

An Email Forum is being developed to promote discussions of interest within the context of gynaecological cancer, research, treatment and care. We hope to launch the Forum on our website in November 2008, initially, as a pilot program to only Study Coordinators. We hope you will find this to be a productive and useful tool to foster wider communication with your ANZGOG colleagues. You will be notified when the Forum is made live.



## Recruitment Update

Well done to our six highest recruiting sites for our currently active trials:

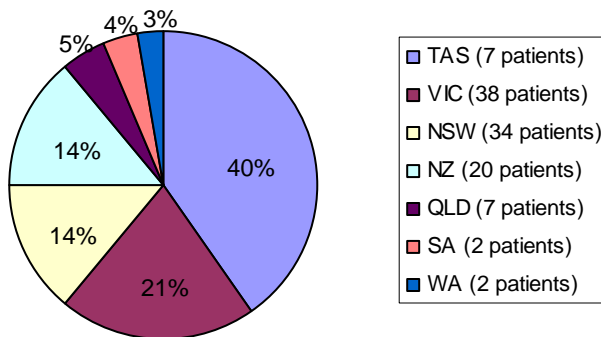
Prince of Wales/Royal Hospital for Women (15)  
 Monash Medical Centre (12)  
 Calvary Mater Newcastle (9)  
 Royal Women's Hospital (9)  
 Christchurch Hospital (8)  
 Waikato Hospital (8)

Between them, these six sites have contributed 56% of the patients to our open trials—namely SCOTROC-4, TRIPOD, ICON-7, Symptom Benefit and PORTEC-3.

We have recently analysed recruitment to our current trials on a per state/country basis, and with the Olympics still fresh in our minds, we are presenting our figures adjusted per head of population. On that basis, Tasmania comes out way on top, so congratulations to Dr Penny Blomfield and her team at Royal Hobart Hospital for their great work. Of course there are many more demographic factors than just population that come in to play here — we definitely value the contributions that all of you make equally!



Percentage of patients recruited, adjusted for population



### Screening aids:

We are pleased to be able to provide sites with these very stylish compendiums, screening pads and pens, thanks to funding received from Cancer Australia. Please keep these handy and complete a screening note every time a potential patient is seen, then return to the ANZGOG Coordinating Centre.



We are currently finalising a **pilot** program to allocate the funding received from Cancer Australia to assist with travel and accommodation costs for clinical trial participants from rural and regional areas attending their trial treatment visits.

The **pilot** program will target only ICON7 trial participants in 6 sites. Each selected site will be contacted directly to undergo a Program orientation prior to program commencement in October 2008.



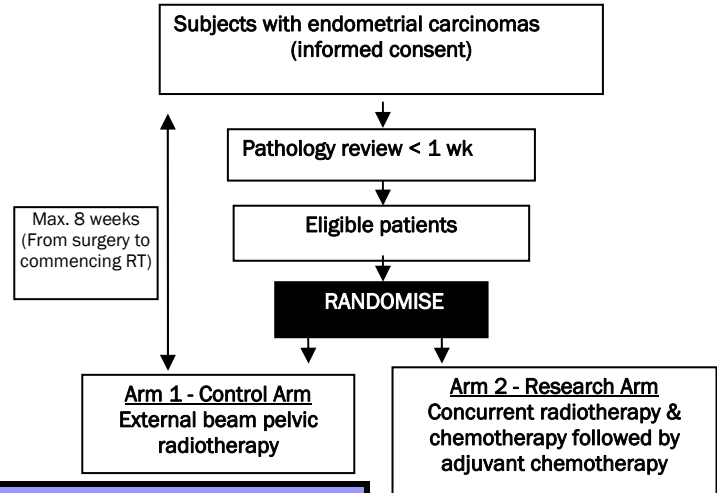
## PORTEC-3

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

#### Objectives:

**Primary** - Overall survival and failure-free survival

**Secondary** - Rates of treatment-related toxicity, quality of life and pelvic and distant recurrence



PARTICIPATING SITE	PI	Activation Date
Calvary Mater Newcastle	Dr Anne Capp	
Christchurch	Dr Michelle Vaughan	25/07/08
Launceston	Dr David Byram	On hold
Mater Adult Brisbane	Dr Paul Mainwaring/Dr Jonathan Ramsay	
Monash Medical Centre	Dr Pearly Khaw/ Dr Geraldine Goss	
Palmerston North	Dr Claire Hardie	Initiation scheduled 12/09/08
Peter MacCallum	Dr Linda Miles hkin – Study Chair	
Prince of Wales/RHW	Prof Michael Friedlander	
Royal Adelaide	Dr Scott Carruthers	02/09/08
Royal Brisbane	Dr Robyn Cheuk	
Royal Hobart	Dr Penny Blomfield	
Royal North Shore	Dr Gillian Lamoury	
Royal Prince Alfred	Prof Chris Milross	
Sir Charles Gairdner	Dr Martin Buck	
Waikato	Dr Ruth Angell/ Dr Marion Kuper	03/09/08
Wellington	Dr Carol Johnson	11/07/08
Westmead	Dr Gerard Wain	
Wollongong	Dr Amanda Glasgow/ Dr Kerwyn Foo	01/09/08

#### Trial Coordinator

**Sarah Chinchen**  
**Email:**  
 schinchen@ctc.usyd.edu.au  
**Phone:** 02 9562 5066



## PORTEC-3

### Current Status

- We now have 5 active centres in Australia and New Zealand
- **Wellington Hospital** was the first ANZGOG site to be activated. We would like to thank the team at Wellington, especially Debra Morriss and Maureen Blakemore for coordinating the New Zealand ethics application
- **Wollongong** and **Royal Adelaide** were the first Australian centres to be activated in early September

The trial has TROG approval and the collaborative group agreement with TROG is currently being finalised.

### Recruitment

Internationally PORTEC-3 is hoping to recruit 500 patients over 5 years. If the rate of recruitment is > 100/year, this number may be increased to 800.

Our ANZGOG target is 50 patients per year—this requires each site to contribute just 3 patients per year.

- 27 patients have been recruited internationally (as at 23<sup>rd</sup> July) and we are looking forward to putting the first ANZGOG patient on the trial.

### ANZGOG sub-study

A patient preferences sub-study was submitted to Cancer Institute NSW for approval. This will look at the benefits patients and their doctors judge necessary to make chemotherapy worthwhile and will involve patient and physician questionnaires. More information on this will be sent to sites soon.

**Thank you to Sonya Stephens, PORTEC-3 Trial Coordinator from Royal Adelaide Hospital who shares the following with us:**

While attending the National Cancer Institute of Canada (NCIC) Spring Meeting which was held in Toronto in May this year as part of my role as Central Trial Coordinator of an International Collaborative Group Trial, I took the opportunity to attend the PORTEC-3 start up meeting where I met Carien Creutzberg. The agenda of the meeting was quite short, starting with Carien giving an overview of the trial which also covered the results of the trials which then led to the development of the PORTEC-3 trial which proved to be quite interesting. It was noted that age was a significant prognostic factor in determining the risk factors for loco-regional relapse. It has also been shown that adjuvant chemotherapy should be multi-agent and the best include platinum and Paclitaxel. The next part was looking at the study treatment issues of chemotherapy and radiotherapy which covered dose reduction for chemotherapy if required and the use of docetaxel if the patient proves to be hypersensitive to paclitaxel and the planning process for radiotherapy. The next part was safety reporting and that is looking at how we are to report any adverse events and the process is the same the world over.

It was interesting to note that many of the processes that Canada and the NCIC are going to use to get the study up and running, are the same as what we will also be doing here as part of ANZGOG and the CTC. For a study to run in Canada there needs to be a central approval and activation before the individual sites get local approval, the same as we did with getting approval in NSW prior to the individual sites putting the trial to their Ethics Committees. Also the enrolment process will be the same with the NCIC Clinical Trials Group (NCIC CTG) wanting the sites to fax them the checklist and pathology review form as well as the consent signature page prior to them randomising the patient. As with the NHMRC CTC all communications with the centres will be channelled through the CTG office from the Central Trial Office. This helps when there have been questions about eligibility or timing of procedures as both the CTC and CTG can ensure that all of the requirements have been set in place for the patient to be randomised on the study.



## SYMPTOM BENEFIT

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

**The aim of this study** is to develop a strong measure of benefit of chemotherapy, which takes into account subjective and objective responses; as well as to understand the emotional and physical price paid by women with recurrent ovarian cancer.

#### Current Status

The Symptom Benefit study opened at RPAH on 8<sup>th</sup> May 2008 and there are now four sites opened to recruitment with two more sites scheduled to open soon. All sites for Stage 1 will then be open for recruitment with a target of 50 patients.

The Symptom Benefit study is a collaboration between ANZGOG and PoCoG and in Stage 2, will include other GCIG members as well. It is the first internationally collaborative GCIG study led by ANZGOG. The recruitment target for stage 2 is 600 patients. Additional sites in ANZ and other GCIG groups will participate in Stage 2 of this trial.

#### Stage 1:

PARTICIPATING SITE	PI	Activation Date	Patients
Illawarra Cancer Centre, Wollongong	Dr Amanda Glasgow	12/06/2008	
Prince of Wales/RHW	Prof Michael Friedlander- Study Chair		
Royal Prince Alfred	Dr Philip Beale	08/05/2008	1
Westmead	Dr Paul Harnett		
Royal North Shore	Dr Sally Baron-Hay		
Princess Margaret, Toronto, Ontario	Dr Amit Oza	16/07/2008	
Juravinski Cancer Centre, Hamilton, Ontario	Dr Laurie Elit	12/06/2008	2

**Trial Coordinator**  
Email:  
Phone:

**Kim Gillies**  
kgillies@ctc.usyd.edu.au  
02 9562 5032



## TRIPOD

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

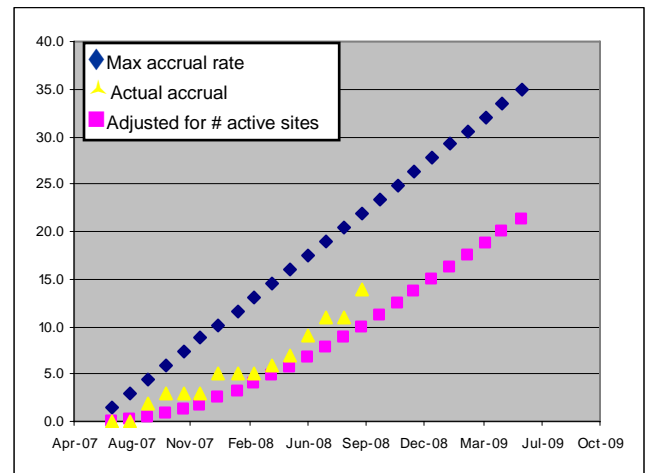
PARTICIPATING SITE	Activation Date	Patients
Border Medical Oncology	21/04/2008	
Flinders Hospital		
Liverpool Hospital		
Mater Adult, Brisbane	21/11/2007	4
Mercy Hospital for Women, Melbourne	3/03/2008	
Prince of Wales/RHW	16/08/2007	3
Royal Adelaide Hospital	11/07/2007	
Royal Hobart Hospital	25/01/2008	3
Royal North Shore Hospital	20/06/2008	
Royal Prince Alfred Hospital		
Royal Women's Melbourne	21/06/2007	1
Sir Charles Gairdner Hospital	10/12/2007	
Westmead Hospital	10/06/2008	
NEW ZEALAND		
Christchurch		
Wellington		
<b>TOTAL</b>		<b>11</b>

### Current Status

TRIPOD opened to recruitment in June 2007 and we currently have ten active sites and eleven patients recruited.

TRIPOD will have an interim analysis after the 15th patient has completed treatment

**Late breaking news!** — 3 patients already for September has us much closer to our interim analysis



**Trial Coordinator**  
Email:  
Phone:

**Kim Gillies**  
kgillies@ctc.usyd.edu.au  
02 9562 5032



## ICON7

A randomised (1:1 ratio), 2 arm, multi-centre, GClG 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.

PARTICIPATING SITE	Site No	Activation Date	Patients
Border Medical Oncology	11001	17/09/2007	3
Box Hill Hospital	11002	29/04/2008	1
Canberra Hospital	11021		
Liverpool Hospital	11004		
Mater Adult Brisbane	11005		
Mercy Hospital for Women	11006	30/11/2007	1
Calvary Mater Newcastle	11007	10/04/2008	2
Prince of Wales/RHW	11008	09/10/2007	7
Royal Adelaide Hospital	11009	19/09/2007	2
Royal Brisbane & Women's Hospital	11010	14/03/2008	
Royal Hobart Hospital	11011	21/01/2008	3
Royal North Shore Hospital	11012	27/11/2007	1
Royal Prince Alfred Hospital	11013		
Royal Women's Hospital	11014	30/10/2007	7
Sir Charles Gairdner Hospital	11015	10/03/2008	2
Westmead Hospital	11016		
Wesley Medical Centre	11017	02/07/2008	1
Lismore Base Hospital	11018	12/03/2008	1
Christchurch	17002	07/04/2008	4
Dunedin	17003	20/08/2008	
Wellington	17004	14/04/2008	
<b>TOTAL</b>			<b>35</b>

### Current Status

Australia and New Zealand now have sixteen active sites with a total of thirty-five patients recruited.

There are many Study Aids on the ANZGOG website:  
**[www.anzgog.org.au](http://www.anzgog.org.au)**

These are located in the secure members' area and you will need to log on with your userid and password.

ANZ target accrual = 90  
Total accrual = 1520  
International Accrual as at 27 August 2008 = 1004

ICON7 is scheduled to close to recruitment in March 2009

**ICON7**  
Bevacizumab in Ovarian Cancer

The latest news and information regarding this study can be found at <http://www.icon7trial.org/> by logging on to the Collaborators area with the following:

Username: icon7\_inst  
Password: 1con7\_in2t

Trial Coordinator  
Email:  
Phone:

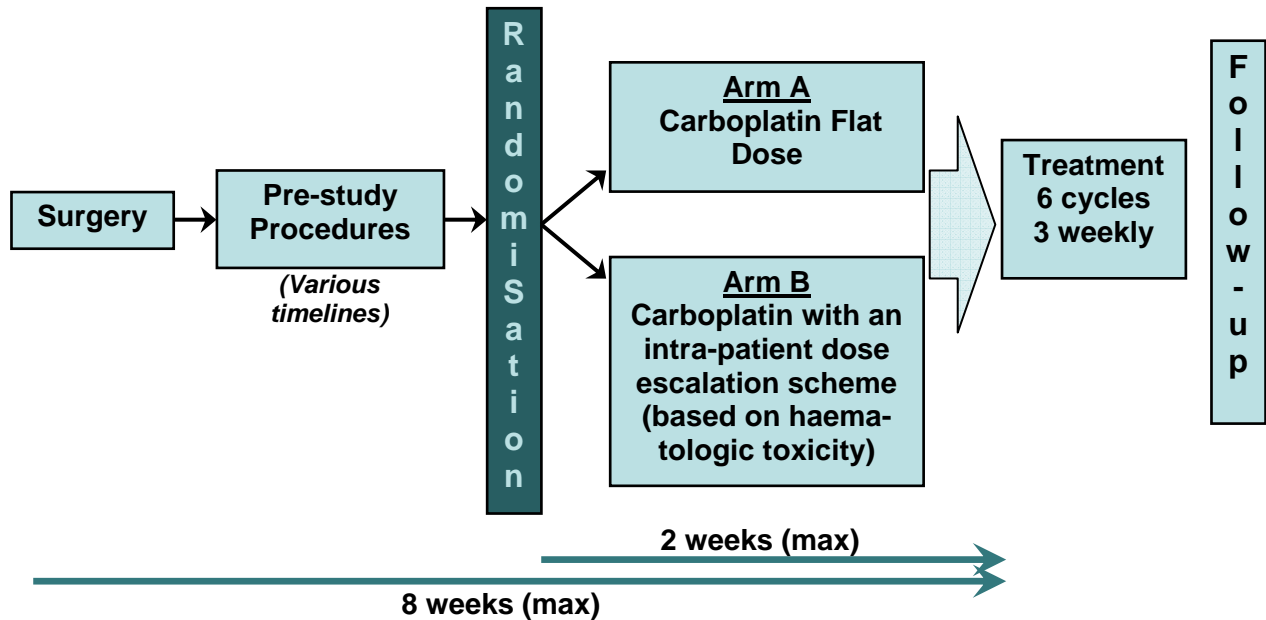
Kim Gillies  
[kgillies@ctc.usyd.edu.au](mailto:kgillies@ctc.usyd.edu.au)  
02 9562 5032



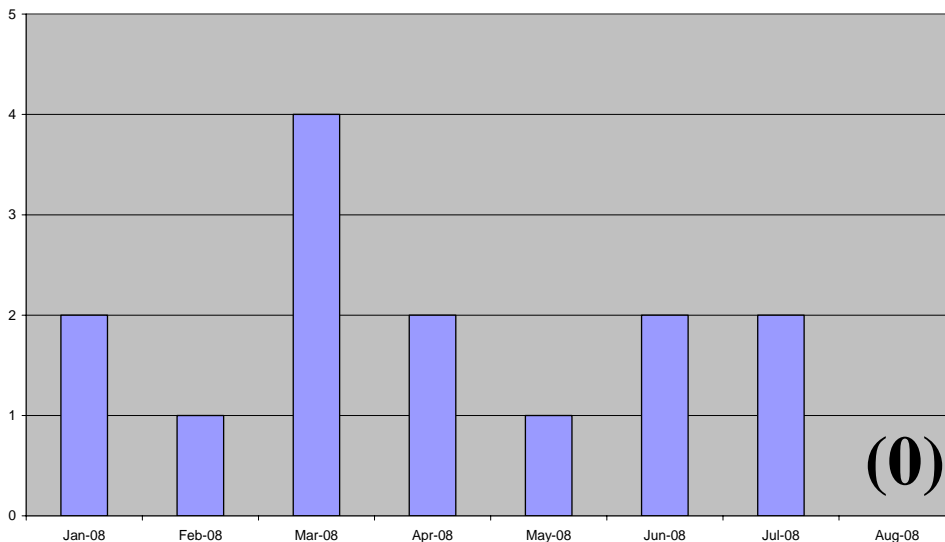
## SCOTROC-4

### 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

We welcome Dr. Amanda Goldrick and her team at Liverpool Hospital onto the trial who were activated in August 2008.



### Recruitment January - August 2008



PARTICIPATING SITE	Patients
Auckland	2
Ballarat	1
Border	1
Box Hill	6
Calvary Mater	7
Christchurch	4
Frankston	1
Lismore	1
Liverpool Hospital	
Manning Base	
Mater Adult Brisbane	
Mercy for Women	1
Monash	12
Prince of Wales/RHW	5
Royal Brisbane	1
Royal Hobart	
Royal North Shore	5
Royal Women's	1
SHOC	
Waikato	8
Wellington	1
Westmead	1
<b>Total</b>	<b>58</b>

**Trial Coordinator**

**Email:**

**Phone:**

**Raymond Tangunan**

[rtanganan@ctc.usyd.edu.au](mailto:rtanganan@ctc.usyd.edu.au)

+612 9562 5044



## CALYPSO

Closed to Recruitment Worldwide: 25 September 2007  
Total Recruitment: 976

A total of 71 patients were recruited in ANZ, only about 50% of the numbers anticipated.

All patients in ANZ have completed treatment, 22 patients are deceased and 49 are in follow-up phase (15 not progressed).

### ATTENTION!

Sites are reminded that there will be a partial data lock at the end of September, early October. This will coincide with the last patient worldwide completing study treatment and enable analysis of the data for the 2009 ASCO conference in May. There will be ongoing follow-up of data entry and queries in the lead-up to this data-lock and all sites are asked to please keep up to date with both.

### GENERIC AND PRINCEPS SUBSTUDY

Due to the higher rate of allergic reaction observed in the paclitaxel arm (19% grade 2-3-4) compared to the Caelyx arm (6%), it was decided to collect retrospectively and prospectively the type (generic or princeps) of paclitaxel and carboplatin for each patient of the study in order to check if this difference in frequency could be due to an interaction with paclitaxel's excipients which may be slightly different in terms of purity between princeps and generics.

Trade names were collected for more than 70% of the patients. 15 different generics were used for carboplatin and 10 for Paclitaxel. Comparison was made between the rate of allergic reactions and the occurrence of the drugs used. No significant difference was observed between the different generics and princeps, neither for carboplatin nor for paclitaxel.

#### Data Management:

Please remember to validate eCRFS once they are complete and you have checked your entries. For sites using paper CRFs, once again, please submit these to the CTC in a timely manner.

**Trial Coordinator:** Kerri Carlton  
**Email:** kcarlton@ctc.usyd.edu.au  
**Phone:** +61 2 9562 5067

## ACCELERATED BEP

### Current Status

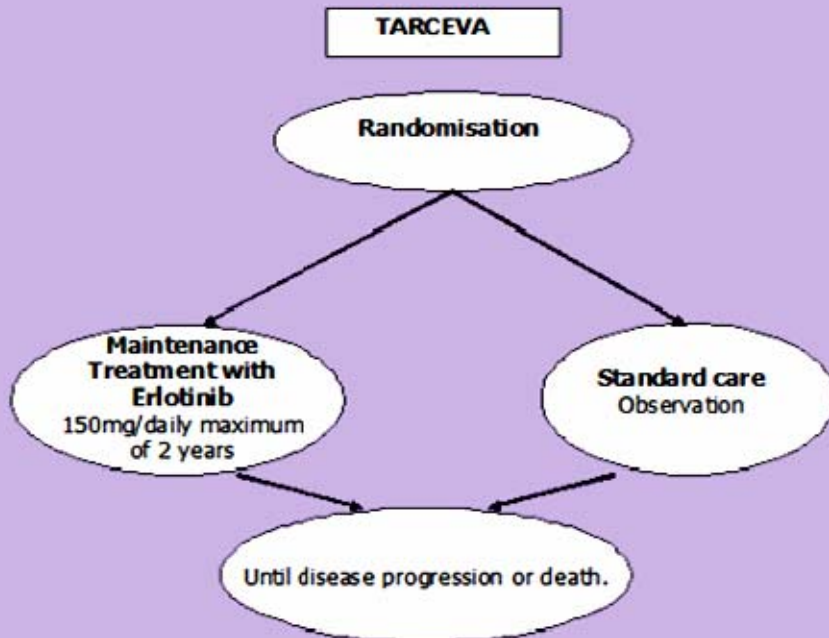
- Recruitment is now at 9 patients from a total target of 25 for this **ANZ Germ Cell Trials Group/ANZGOG Intergroup collaboration**.
- The trial is open at 13 sites, with 2 further sites pending activation in 2008 (Flinders & University of Southern California).

**Trial Coordinator** Amy Boland  
**Email:** BEP@ctc.usyd.edu.au  
**Phone:** +61 2 9562 5059



## 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

Closed to Recruitment:  
19<sup>th</sup> February 2008

Final Accrual:  
835 patients

ANZ total Recruitment:  
42 patients

### CRFs

Thanks to you all for your timely submission of CRFs. ANZGOG sites are very compliant, with few overdue forms or queries. Please keep forwarding due CRFs at your earliest convenience to maintain our good track record.

### ANNUAL REPORT to HREC

If your annual report for the study is due please submit that too and send a copy of the approval letter to ANZGOG. We will be sending reminders as your annual report falls due.

### REMINDER

It is important to track translational research samples collected for TARCEVA on the Virtual Tumour Bank regularly and send them in batches to EORTC. Currently only tissue blocks and slides are to be sent; packaging and courier instructions for plasma and blood samples will be sent to all the participating sites at a later date. Once samples have been received at the EORTC you will be eligible to receive an additional payment based on the type and number of samples sent.

Thank you for participation in this important study!

**Clinical Trial Assistant:**  
**Email:**  
**Phone:**

**Mausam Doctor**  
mdoctor@ctc.usyd.edu.au  
**02 9562 5085**



## GOG 182

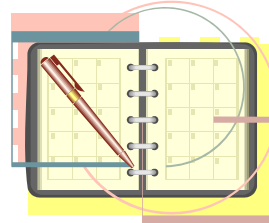
### GOG 182

Opened to recruitment: June 2002

Closed to recruitment: Sep 2004

183 patients recruited in ANZ across 26 sites.

75 patients are currently in follow-up and they will be followed up for life.



### Q Forms

Patients are followed up for scheduled appointments and a forms schedule is sent to each site on a monthly basis. Please ensure your patients follow this schedule and the appropriate Q forms are completed at each visit.

Due to US regulations, both GOG studies are required to have annual ethics renewals. Reminders have been sent regarding this so please follow up with your ethics committees as appropriate.

## GOG 199

### GOG 199

Closed to recruitment: November 2006

83 patients recruited across 4 Australian sites.

We continue to work closely with site staff and the ABN Tissue Bank in Melbourne to ensure timely delivery of samples.



**Trial Coordinator**  
**Email:**  
**Phone:**

**Kim Gillies**  
**kgillies@ctc.usyd.edu.au**  
**02 9562 5032**