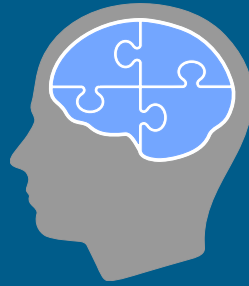


Quick Update:

- Membership: 413 members
- Very successful 2014 ASM



COGNO

COOPERATIVE TRIALS GROUP
FOR NEURO-ONCOLOGY

Member Newsletter

Issue 17

Summer 2014 / 15



Message from our Chair

Welcome to the final Newsletter for 2014 and once again I can confidently boast about COGNO activities and feel secure about our future.

As you will read below, COGNO has had another successful ASM, increased our Membership and has a number of new trials in the pipeline for 2015. In addition, your COGNO Executive have been busy attending meetings seeking new trial opportunities. Increasingly, the large groups such as the EORTC, NCIC and the US groups see COGNO as an important contributor to neuro-oncology clinical trials. They have welcomed us to their own scientific and business meetings.

Looking forward, we are planning to have our second "Ideas Generation Workshop" and the 2015 ASM Committee, led by Convenor Cecelia Gzell, are hard at work. Indeed, we are already thinking further ahead to the 2016 ASM which will also incorporate ASNO 2016 (Asian Society for Neuro-Oncology). This should attract neuro-oncologists from over 27 countries and will be a major event for all involved.

I wish everyone a great holiday season and hope that you all get some time away from work.

Thanks to everyone on the COGNO Executive and at Operations: a wonderful and enthusiastic team that have done so much to improve the care of our patients.

Mark Rosenthal
Group Chair

Inside this issue:

Chairman's Message	1
COGNO 7 th ASM Report	1, 4-5
CABARET Update	2
CATNON Update	2
SEED Update	2
New Concepts/ Trials in Development	3
Working Groups	3
Membership Update	3
COGNO Team Update	3
Congratulations Denis	3
Quality Of Life (QOL) Office	4
COGNO 8 th ASM Save the Date!	6

7th COGNO ASM

'TRANSLATING SCIENCE TO PATIENT CENTRED TRIALS'

Friday 24th - Saturday 25th October 2014

The Langham, Melbourne, Australia

Congratulations to Co-Convenors Mustafa Khasraw and Zarnie Lwin and the organising committee on a successful ASM! The scientific program, with international speakers Professor Lisa DeAngelis and Professor Minesh Mehta, as well as a number of Australian experts, was well received. Of particular note was the panel discussion facilitated by Ian Kerrigan on "Challenges in attracting clinical trials to Australia".

Congratulations to our award recipients -

Most Outstanding Oral Presentation: Joint recipients Yi Chieh Lim and Cecelia Gzell. Yi's presentation was on *Stem-like Glioblastoma Cells Can Be Targeted With A Novel Radiomimetic Agent With Roles in DNA Double Strand Break Induction and Homologous Recombination Inhibition*, and Cecelia's on *Small increases in enhancement on MRI may predict survival post radiotherapy in patients with glioblastoma*.

(continues on page 4)

STUDY & TRIAL UPDATES

CABARET Study: *A randomised phase II study of Carboplatin and Bevacizumab in Recurrent Glioblastoma Multiforme (GBM)*

The CABARET study was formally closed on the 5 December 2014. Patient status at the time of study closure was as follows:

Patient Status	
On Part 1	2
On Part 2	0
In follow-up	2
Deceased	117
Withdrawn consent	1
Total	122

Patients remaining on treatment at the time of study closure were granted compassionate access to bevacizumab by Roche for ongoing treatment.

The CABARET Trial Management Committee are working on a range of publications, including the primary outcome data, quality of life data, and Part 2 data amongst others. The primary manuscript is near finalised, and we hope to submit for publication in early 2015.

As always, a huge thank you to everyone involved in CABARET for making the study run so smoothly. Our success to date is a reflection of your dedication and commitment. For more information or queries, please contact the team on cabaret@ctc.usyd.edu.au.

CATNON (EORTC 26053-22054): *Phase III trial on concurrent and adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma*

The CATNON study has now randomised 666/748 patients internationally and has registered 1264 patients. 73 patients have been randomised and 160 patients have been registered in Australia alone.

We continue to receive very positive feedback from the Quality Control Coordinator at the EORTC regarding the quality and timeliness of data from Australian sites. This is a reflection of the dedication of staff at sites completing the CRFs and the CATNON team at the CTC, and we thank all those involved for their ongoing efforts to maintain such

high standards.

It is anticipated that the trial will close to recruitment internationally in approximately Q4 2015. We predict that we will be near reaching our target of 100 Australian patients randomised at this time.

As always, the CATNON Trial Coordinator, Lisa Bailey welcomes all suggestions and queries and is happy to provide any assistance required. Please email catnon@ctc.usyd.edu.au with any questions.

CATNON Recruitment by Site

No	Site name	State	Principal Investigator	Date activated	No. of patients registered	No. of patients deemed ineligible	No. of patients randomised
1	Royal North Shore Hospital	NSW	Helen Wheeler	20-Aug-10	39	19	20
2	Royal Hobart Hospital	TAS	Rosie Harrup	8-Sep-10	11	4	7
3	Austin Health	VIC	Lawrence Cher	21-Jun-10	13	11	2
4	Sir Charles Gairdner Hospital	WA	Anna Nowak	29-Sep-10	19	10	9
5	The Alfred	VIC	Sanjeev Gill	31-Aug-11	23	12	11
6	St. Vincent's Hospital Melbourne	VIC	Anthony Dowling	22-Mar-11	19	9	9
7	Royal Melbourne Hospital	VIC	Mark Rosenthal	3-Sep-10	13	8	6
8	Flinders Medical Centre	SA	Ganessan Kichenadasse	26-Jul-11	7	5	2
9	Royal Prince Alfred Hospital/ Chris O'Brien Lifehouse	NSW	John Simes	11-Mar-11	4	1	3
10	Princess Alexandra Hospital	QLD	Katharine Cuff	14-Dec-11	6	4	2
11	Westmead Hospital	NSW	Najmun Nahar	23-Jul-13	4	3	1
12	Prince of Wales Hospital	NSW	Elizabeth Hovey	30-Oct-13	0	0	0
13	Royal Brisbane and Women's Hospital	QLD	Po Ling-Inglis	7-May-14	2	1	1
Current at 2 Dec 2014				Total	160	87	73

SEED Study: *Self-reported evaluation of the adverse effects of dexamethasone*

The SEED study was formally closed to recruitment on 31 October 2013. All patients have completed study visits, all data has been cleaned and the database locked, and the final statistical analysis report has been prepared. Preliminary results were presented at the COGNO ASM in Melbourne in October. The Study Management Committee are in the final stages of drafting the primary manuscript, with aims to submit for publication Q4 2014 - Q1 2015. The SEED team are in the process of closing study sites in preparation for formal study closure in 2015. Results of the study have been used to inform the design of a subsequent phase II trial, which has now been submitted for ethics committee approval, with plans to activate sites approximately Q2 2015. Stay tuned for more information about this new COGNO trial.

NEW CONCEPTS/TRIALS IN DEVELOPMENT

COGNO is very excited to announce 2 trials currently in development.

VERTU: A Randomised Phase II study of veliparib + radiotherapy (RT) with adjuvant temozolomide (TMZ) + veliparib versus standard RT + TMZ followed by TMZ in patients with newly diagnosed glioblastoma (GBM) with unmethylated O (6)-methylguanine-DNA methyltransferase (MGMT). This study will recruit 120 participants with newly diagnosed patients with histologically confirmed GBM (WHO grade IV) following surgery, with unmethylated MGMT promoter gene GBM. The central ethics application was submitted in November. It is anticipated this study will start in early 2015. Feasibility surveys have been completed and final site selection will occur in the near future.

ACED: A Phase II randomised non-comparative placebo-controlled double blind trial of Acetazolamide plus Dexamethasone versus dexamethasone alone for management of cerebral oedema in recurrent and/or progressive High Grade Glioma. This study will recruit 82 participants with GBM, HGG, AA, AO (progressive and/or recurrent disease) who require dexamethasone recommencement or dose increase due to progressive raised ICP. The central ethics application was submitted in November. It is anticipated this study will start in early 2015. Feasibility surveys have been completed and final site selection will occur in the near future.

WORKING GROUPS

Exercise: There has been a lot of interest in the potential role of an up-front exercise intervention in the high grade glioma setting in terms of adding to not only quality of life, but possibly also contributing to survival benefit. Exercise capacity has been demonstrated to be an independent prognostic factor in the glioblastoma setting but a specific exercise intervention has not been formally studied until now. Two non-COGNO Australian pilot studies are taking place to address the feasibility of introducing such an intervention in this setting (during and subsequent to radiation). Anna Nowak and Prue Cormie et al in Perth have been running such a pilot study in Perth since early 2014 and Elizabeth Hovey, Siew Koh, Haryana Dhillon and Fiona Naumann et al have just opened a separate up-front exercise study in NSW and Queensland. There are similarities in designs of the studies, but also novel aspects to each one (eg assessing bone mineral density, and offering patient-carer exercise dyads in the Perth study; and permitting patients with significant neurological deficit such as hemiparesis into the NSW/Queensland study). These 2 groups are coming together under the umbrella of COGNO to apply for 2015 grant funding round for a harmonised Phase III study with Anna Nowak as Australian COGNO PI. If successful, such a study would likely open in 2016.

MEMBERSHIP UPDATE

COGNO now has 413 members! Our numbers are as follows in each of the states and internationally.
Australia: NSW (180), VIC (87), QLD (63), WA (20), SA (19), ACT (12), TAS (12) and NT (1);
International: NZ (8), Singapore (3), Canada (3), Ireland (1), India (1), Sweden (1), Switzerland (1) and USA (1).

COGNO has also extended its Associate Membership category to include consumers, overseas and industry members.

Help us expand our Group's expertise and networking capacity. If you know someone who would like to join, you can refer prospective members to our online membership application on our website (www.cogno.org.au) or office (cogno@ctc.usyd.edu.au).

COGNO Team Update

We say goodbye to Cathy Boreham, SEED study coordinator. Diana Winter will take on board the SEED study coordinator (in addition to her CABARET data manager responsibilities).

Congratulations Denis

Congratulations to Denis Strangman on his well-deserved Society for Neuro-Oncology (SNO) Public Service Award.

Denis addressing the First World Summit of Brain Tumour Patient Advocates which he co-organised, held in California in November 2013
Photograph: Paolo Salcido



MANAGEMENT COMMITTEE

Prof Mark Rosenthal (Chair)
 Prof John Simes (Deputy Chair)
 Dr Liz Hovey (Treasurer)
 Dr Eng-Siew Koh (Secretary)
 A/Prof Meera Agar
 A/Prof Kate Drummond
 Ms Marcia Fleet
 Dr Matthew Foote
 Prof Terry Johns
 Ms Robyn Leonard

SCIENTIFIC ADVISORY COMMITTEE

Dr Liz Hovey (Chair)
 Dr Eng-Siew Koh (Deputy Chair)
 A/Prof Meera Agar
 Ms Alanah Bailey
 Ms Liz Barnes
 A/Prof Kate Drummond
 Dr Matthew Foote
 Dr Lindy Jeffree
 Prof Terry Johns
 Dr Danette Langbecker
 Ms Robyn Leonard
 Mrs Ann Livingstone
 Dr Kerrie McDonald
 Dr Anna Nowak
 Prof Mark Rosenthal
 Dr Gail Ryan
 Prof John Simes
 Dr Helen Wheeler

OPERATIONS EXECUTIVE COMMITTEE

Prof Mark Rosenthal (Chair)
 Prof John Simes (Deputy Chair)
 Ms Liz Barnes
 Ms Jenny Chow
 Mrs Merryn Hall
 Dr Liz Hovey
 Dr Mustafa Khasraw
 Dr Eng-Siew Koh
 Mrs Ann Livingstone
 Ms Kate Sawkins

Quality Of Life (QOL) Office

QOL are contracted by Cancer Australia as providers of the Quality of Life Technical Service to the Australian Cancer Co-operative Clinical Trials Groups (CCTGs) for the period of 1 July 2013 - 30 June 2016.

The QOL Office offers a range of services to members of COGNO, including:

- a number of free web resources, including a checklist of items to include in the QOL sections of your trial protocol, information about common QOL measures and information about how to analyse QOL data;
- an advisory service - to assist COGNO members with their QOL sub-studies;
- regular free training workshops about the concept of QOL and other patient-reported outcomes (PROs), and how to design and conduct QOL/PRO studies.

Additional resources which may be of interest are:

The CONSORT PRO extension

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials (RCTs); however, it lacks guidance on the reporting of patient-reported outcomes (PROs). It is crucial that PRO data are reported with sufficient detail and clarity to ensure their value, interpretation and translation. The CONSORT-PRO extension was developed in 2013. It adds five, PRO-specific items to the CONSORT statement, including identifying PROs as a primary or secondary outcome in the abstract, describing the PRO hypothesis and relevant PRO domains, providing evidence of the PRO instrument's validity and reliability, stating the statistical approaches for dealing with missing data, and discussing the limitations and generalizability of study findings. More information can be found in the publication, which can be freely downloaded at: <http://jama.jamanetwork.com/article.aspx?articleid=1656259#RationaleforaConsortExtensionFocusedonPatient-ReportedOutcomes>.

For more information, please visit the QOL website: pocog.org.au/qoloffice.

7th COGNO ASM

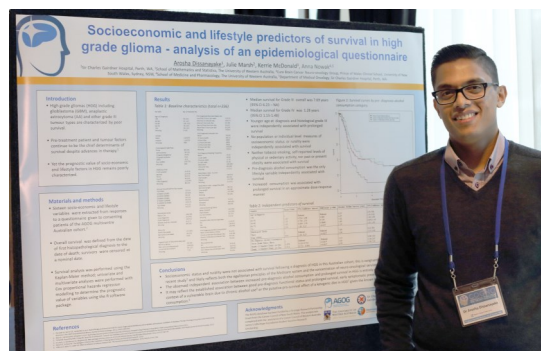
'TRANSLATING SCIENCE TO PATIENT CENTRED TRIALS'

Friday 24th - Saturday 25th October 2014

The Langham, Melbourne, Australia

(continued from page 1)

Most Outstanding Poster Presentation: Joint recipients Arosha Dissanayake and Theo Mantamadiotis. Arosha's poster presentation was on *Socio-economic and lifestyle predictors of survival in high grade glioma - analysis of the Australian Genomics and Clinical Outcomes of Glioma Epidemiological Questionnaire*, and Theo's on *A novel brain cancer mouse model harbouring human-relevant PI3-kinase pathway mutations*.



Arosha Dissanayake at his poster



Theo Mantamadiotis with Mark Rosenthal

(continues on page 5)

7th COGNO ASM
'TRANSLATING SCIENCE TO PATIENT CENTRED TRIALS'
 Friday 24th - Saturday 25th October 2014
 The Langham, Melbourne, Australia

(continued from page 4)



Yi Chieh Lim and Cecelia Gzell with Mark Rosenthal



Left to right: Mustafa Khasraw, Lisa DeAngelis, Minesh Mehta, Zarnie Lwin



Cancer Institute NSW Travel Grant Recipient: Ms Jennifer Brittain

A copy of the ASM conference booklet (including abstracts) is available on <http://www.cogno.org.au/content.aspx?page=cognoasm2014>.

COGNO thanks the following for their support of the 2014 ASM: Cure Brain Cancer Foundation (Gold Sponsor), Roche (Bronze Sponsor and CNS Lunch Symposium Sponsor), MSD Oncology (Bronze Sponsor), Novartis (Bronze Sponsor), State Government Victoria (Bronze Sponsor), Cancer Institute NSW (Travel Scholarship), Brainlab and Cancer Australia.

The COGNO Scientific Program was developed independent of sponsor involvement.



COGNO CONTACTS

Ann Livingstone
 Associate Oncology Program Manager - Development
 (Mon, Tue, Thur, Fri)
 E: ann.livingstone@ctc.usyd.edu.au
 T: (02) 9562 5332

Kate Sawkins
 Associate Oncology Program Manager - Operational
 E: kate.sawkins@ctc.usyd.edu.au
 T: (02) 9562 5374

Diana Winter
 CABARET Data Manager
 (Tue, Thur, Fri)
 E: cabaret@ctc.usyd.edu.au
 T: (02) 9562 5393

Lisa Bailey
 CATNON Trial Coordinator
 (Mon, Tue, Wed)
 E: catnon@ctc.usyd.edu.au
 T: (02) 9562 5364

Diana Winter
 SEED Study Coordinator
 (Tue, Thur, Fri)
 E: seed@ctc.usyd.edu.au
 T: (02) 9562 5311

Mustafa Khasraw
 CTC Clinical Lead for COGNO
 E: mustafa.khasraw@ctc.usyd.edu.au

Jenny Chow
 Executive Officer (Mon, Tues, Wed)
 E: cognoeo@ctc.usyd.edu.au
 T: (02) 9562 5389

Yi Feng
 Admin Assistant (Wed afternoon, Thur, Fri morning)
 E: yi.feng@ctc.usyd.edu.au
 T: (02) 8036 5238

Hannah O'Riley
 Admin Assistant (Wed, Thur)
 E: hannah.o'riley@ctc.usyd.edu.au
 T: (02) 8036 5237

COGNO Coordinating Centre
 NHMRC Clinical Trials Centre
 Locked Bag 77
 Camperdown NSW 1450
 T: +61 2 9562 5000
 F: +61 2 9562 5094
 E: cogno@ctc.usyd.edu.au



Australian Government
 Cancer Australia

COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY

The achievement of better health outcomes for patients and those affected by brain tumours through clinical trials research

www.cogno.org.au

email: cogno@cogno.org.au | tel:02.9562.5000

8th COGNO ANNUAL SCIENTIFIC MEETING

SAVE THE DATE!

FRIDAY 23rd — SATURDAY 24th OCTOBER 2015
BRISBANE, QUEENSLAND, AUSTRALIA

CONFIRMED INTERNATIONAL SPEAKERS



PROF MARTIN J VAN DEN BENT MD



PROF KENNETH D ALDAPE MD



COGNO

COOPERATIVE TRIALS GROUP
FOR NEURO-ONCOLOGY