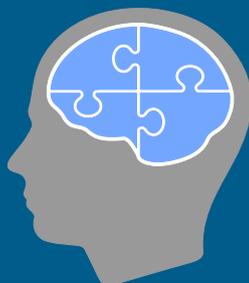


Quick Update:

- Membership: 624 members
- 10th COGNO ASM website launched



COGNO

COOPERATIVE TRIALS GROUP
FOR NEURO-ONCOLOGY

Member Newsletter

Issue 25

Winter 2017

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Message from our Chair



Dear COGNO members,

This newsletter seems to roll around every few weeks and immediately I wonder whether I have any news to tell. Well this time there are a few of the routine items to note, and, at the end of my report, a major announcement.

John Simes, Siew Koh and I had the honour of representing COGNO before the Senate enquiry into tumours with poor outcomes. There were over 250 submissions and a number of days of interviews. For me, it was a novel experience: very formal in some ways and relaxed in others. It is a little humbling to read the Hansard version of my own speech and the answers I gave as it draws attention to how one speaks in public. Naturally John Simes was in his element but I was particularly proud of Siew as I gave her only 30 seconds notice to give a three-minute speech to the Senators and her Hansard records her as word perfect. The Senators were engaged, asked excellent questions and I believe there is genuine regard for improving support for research into tumours like the ones we manage. The Senate enquiry transcript is [available here](#).

This newsletter provides the usual information regarding trials, membership, workshops and the upcoming ASM. Our organising committee have done a great job with respect to the program and bringing some International stars to Melbourne and I encourage you to attend. We have also included an interview I did with myself as part of our regular "getting to know you" series.

Finally, I will use this newsletter as the means to publicly announce that I will be stepping down as COGNO Chair at the next Annual General Meeting to be held in conjunction at the October ASM in Melbourne. I have had the pleasure and honour of serving as your Chair since our inception over eight years ago. But from the very first day, I was thinking about a succession plan. You can read a little more about my thoughts and thanks below.

I notified the COGNO Management Committee, and according to the COGNO Charter, the Management Committee elects the Chair from within the Committee through a formal process including a call for nominations and a secret ballot overseen by the Executive Officer. I am delighted to report that Anna Nowak was elected by the Management Committee to replace me as Chair.

This requires ratification by the COGNO membership at the next AGM so, for the moment, I remain as Chair and Anna now sits on the COGNO Operations Executive as the "Chair-elect" until the AGM. I believe that this will assist in a smoother transition and bring Anna up to speed prior to her becoming Chair. I have no doubt that Anna will be a wonderful Chair and warmly congratulate and thank her for taking on this role on behalf of us all.

Mark Rosenthal
Group Chair

10TH COGNO ANNUAL SCIENTIFIC MEETING
Tailoring therapies for brain tumours: challenges and opportunities
Monday 23rd - Tuesday 24th October 2017
Rydges Melbourne, Victoria, Australia

We are pleased to announce the launch of the 2017 ASM website! Registration for the ASM is now open and we draw your attention to these important dates:

Early Bird Registration Closes	21 Jul 2017
Abstract Submission Deadline	21 Jul 2017
Young Investigator Award Submission Deadline	21 Jul 2017
Abstract Presenters Notified	Aug 2017
Deadline for Abstract Presenters to Register	25 Sep 2017
Online Registration Closes	6 Oct 2017
COGNO Annual Scientific Meeting	23-24 Oct 2017

A preliminary program is available on the [program page](#). Take advantage of the early bird registrations and [register now](#). Don't forget to [submit your abstract](#) by 21 July.

GETTING TO KNOW COGNO'S MANAGEMENT COMMITTEE MEMBERS

Professor Mark Rosenthal is the COGNO Chair and a member of numerous COGNO committees.

How did you get involved in COGNO?

Some of my work and personality traits mean I am good at getting things started: organised, passionate, decisive, and collaborative. Being bossy and wanting to be in control also helps! I was the first Chair of the Victorian neuro-oncology group, the COSA neuro-oncology group and then became the inaugural Chair of COGNO when it was established in 2007. I also have enough self-awareness to know what I am not good at; so I try and surround myself with those who can cover for my inadequacies. In the case of COGNO, I was blessed to have such a brilliant, iconoclastic, and idiosyncratic Operations Executive of John Simes and Liz Hovey supported in the first instance by Ann Livingstone and then Jenny Chow and her team.

How did you get interested in brain cancers.

In the late 1990s, neuro-oncology had almost zero profile, no trials and there were only a handful of neurologists caring for patients. I spent two years in New York becoming a "prostate cancer doctor" (another neglected area); but my boss, the revered Franco Muggia, suggested that I work in neuro-oncology as well. It seemed like a good idea, particularly given that I was returning to Royal Melbourne Hospital with its very large neurosurgical unit.

Despite the tremendous support of Andrew Kaye, the early years were difficult: no one to teach, mentor or support me. But by the mid-2000s, there were significant numbers of younger medical oncologists taking an interest due to the need for someone to prescribe the new chemotherapy drug Temozolomide.

What do you like about neuro-oncology?

My professional life is busy, has many components, and, despite occasional dramas, is very fulfilling, enjoyable and rewarding: running a large trials unit, clinical work, committee work, strategic retreats, teaching, mentoring, administrative work, sitting on an ethics committee, clinical research, attending meetings and innumerable interactions within my Unit, my hospital, between hospitals, with pharma and across the nation and the oceans.

But the highlight of my week for nearly 20 years remains my Monday morning Royal Melbourne Hospital brain cancer clinic preceded by our multi-disciplinary (MD) meeting. Why? Because our MD team, led by Kate Drummond, provides extra-ordinary care to some of the most disadvantaged and vulnerable people of Melbourne. They are from the Western suburbs and are unfortunate to have one of the most feared illnesses of all: brain cancer. We provide the very best of care in a timely and compassionate manner. Our patients, like those at your hospitals, are given opportunities that reflect a significant change in practice: outstanding radiology, first class multidisciplinary meetings, care coordinators, multi-disciplinary clinics, clinical trials including experimental Phase 1 studies and direct and efficient referral to all sub-specialties including palliative care.

Most of all I love seeing patients and finding something to chat about and learn from them: the derivation of their name, their work, elements of their life history, which footy team they barrack for, their favourite Elvis song and commonly I have arguments with them as to who has the crazier teenage daughters. And we laugh and laugh about life and its ups and downs.

(continues on page 3)

GETTING TO KNOW COGNO'S MANAGEMENT COMMITTEE MEMBERS

(continued from page 2)

And I get tremendous professional satisfaction from being able to break bad news. I know I can't do open heart surgery or treat hepatitis. And, like all of you, most of what I have learnt I have forgotten. But, I also know that very few can do what many of us do every clinic: break bad news in a compassionate and honest manner. And then comes a remarkable thing: I get to see the human spirit at its finest: gracious, courageous, unflinching and often with a joke at the most dire of moments. What a privilege!

What is your proudest professional achievement?

When guest speakers are introduced at conferences the Chairman gives a typical "bio" presentation that goes something like this: Professor Mark Rosenthal has done this and that, he did a PhD, trained in New York, has over 150 published papers, been the Principle Investigator on innumerable clinical trials, run a Medical Oncology Department, sits on a million committees, Chairs this that and the other, is now Director of Australia's largest trials Unit.

Unquestionably my greatest professional achievement was not a solo effort and was achieved only through the passion and commitment of a small number of collaborative multi-disciplinary colleagues from around Australia. It was a simple and yet profound achievement.

What was it? It was to take a long term and committed interest in patients with brain cancer. As a consequence, we have improved their care immeasurably. For so long, our patients, their families and carers received inadequate attention and care despite the best efforts of those who went before us. Our patients were deemed "too hard", "untreatable" and no one seemed to be paying them appropriate interest and respect. Compared to many other cancer patients they were neglected and ignored.

It took 10 years for our activists to bring neuro-oncology to an appropriate level of awareness. Now, clinical care from diagnosis to death is unrecognisable from what many of us witnessed in the late 1990s. And as a corollary, there have been rapid advances in scientific knowledge from the basic to the translational and to the clinic.

As for my everlasting belief in the primacy of clinical trials? Individuals, collectives and COGNO itself can proudly say that the neuro-oncology trial landscape has irrevocably changed. We now offer options, opportunities, hope and optimism to our wonderful brave patients.

I believe COGNO has played a vital role in establishing and nourishing the Australian neuro-oncology field. Our success as an organisation is directly attributable to the membership, consumers and committees. But can I particularly single out John and Liz who caught the first train with me when we nervously left the station 8 years ago. They have been wonderful executive officers and the three of us have enjoyed a close, effective and genuinely warm relationship. Ann Livingstone helped us board the train, kept us on the righteous path and appropriately figures prominently in our early history. And then accolades to Jenny don't capture my regard and thanks: she laughs at my jokes, seems to know the answer before I have thought of the question, has never been flustered and at all times kept the wheels oiled, the locomotive fired up, the passengers content and kept us in fine regulatory, reporting and financial health.

So that's it. Eight years later I think I can say to COGNO, on behalf of everyone: a job well done. But now time to reflect and re-think. I'm so happy to have played my role but my time as Chair is up and I leave COGNO in the capable hands of Chair-Elect, Anna Nowak.

STUDY & TRIAL UPDATES

*** NEW TRIAL ***

NUTMEG (COGNO 16/01): A Randomised Phase II Study of Nivolumab and Temozolomide vs Temozolomide alone in newly diagnosed Elderly patients with Glioblastoma (NUTMEG)

The NUTMEG trial aims to determine the activity of nivolumab added to adjuvant Temozolomide (TMZ), as measured by overall survival (OS) in GBM patients who are 65 years of age or older.

Glioblastoma (GBM) is the most common type of primary brain tumour and patients diagnosed with this tumour have a poor prognosis. Prognosis is particularly poor for older patients and this population comprise a significant proportion of GBMs. The current standard treatment for this patient group is TMZ with short course radiotherapy

(RT) and has a reasonable survival benefit.

The programmed death-1 receptor (PD-1) is a key target in reactivation of immune response against cancer. GBM tumour cells and infiltrating T lymphocytes express PD-L1, suggesting that immune suppression may be active in GBM. Nivolumab is a humanised monoclonal antibody targeting PD-1, approved in cancers such as melanoma, and with an established safety profile including combination with TMZ in GBM.

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(NUTMEG continued from page 3)

NUTMEG will test whether the addition of nivolumab to adjuvant TMZ in GBM patients who are 65 years of age or older, and have completed short course chemoradiation, will provide further survival benefit.

The NUTMEG trial aims to recruit 102 patients with newly diagnosed histologically confirmed supratentorial GBM (WHO Grade IV malignant glioma including gliosarcoma) who are aged 65 years or older with no previous treatment for GBM other than surgery. Patients will be randomised to experimental treatment or standard treatment in a 2:1 ratio, prior undergoing radiotherapy. All patients will undergo a 3 week course of chemo-radiotherapy (RT: 40Gy/15# + TMZ: 75mg/m² OD). Patients randomised to the experimental treatment will then receive up to 6 cycles of Nivolumab (C1-4: 240mg IV d1 & d15 q4w, C5-6:

480mg IV d1 q4w) + TMZ (C1:150mg/m² OD d1-5 q4w, C2-6*:200mg/m² OD d1-5 q4w). Patients randomised to the standard treatment will instead receive up to 6 cycles of TMZ alone (C1:150mg/m² OD d1-5 q4w, C2-6*:200mg/m² OD d1-5 q4w).

(*increase TMZ to 200mg/m² as tolerated).

The trial will be opened in up to 18 sites across Australia and possibly New Zealand. The trial is currently in its start-up phase and is in the process of site selection. The protocol is currently under review by the responsible Human Research Ethics Committee and we expect to activate the first sites in Q3 of 2017.

The NUTMEG Trial Coordinator is more than happy to provide any information that you may require on this study. Please email nutmeg@ctc.usyd.edu.au if you have any queries.

ACED (COGNO14/02): Phase II randomised placebo-controlled, double blind, multisite study of acetazolamide versus placebo for management of cerebral oedema in recurrent and/or progressive HGG requiring treatment with dexamethasone

The ACED study aims to recruit 84 patients across 12 sites.

The ACED study is now open for recruitment at 5 sites of the 11 selected sites. The trial is currently experiencing slow recruitment but to date, we have randomised 5 patients and sites are actively looking for patients to recruit. The study team is working with the Trial Management Committee to ensure high level of support is provided to the sites.

The study team continues to work diligently with the remaining sites in start-up to ensure they are activated as soon as possible to aid in recruiting more patients into the study.

We are in the process of selecting the final site for the study. If you think your site might be interested in participating, please contact the study team.

Please email aced@ctc.usyd.edu.au if you have any queries.

ACED - PARTICIPATING SITE STATUS						
No	Site name	State	Principal Investigator	Site status	Site activation	# Patients randomised
1	Liverpool Hospital	NSW	Eng-Siew Koh	Active	24/Jun/2016	3
2	Royal Brisbane and Women's Hospital	QLD	Zarnie Lwin	Active	30/Sep/2016	2
3	St Vincent's Hospital, Melbourne	VIC	Anthony Dowling	Active	14/Nov/2016	0
4	Epworth Healthcare	VIC	Ross Jennens	Active	20/Feb/2017	0
5	Sir Charles Gairdner Hospital	WA	Anna Nowak	Active	4/Apr/2017	0
6	Princess Alexandra Hospital	QLD	Katharine Cuff	SSA in progress	Pending	-
7	Prince of Wales Hospital	NSW	Elizabeth Hovey	SSA in progress	Pending	-
8	Flinders Medical Centre	SA	Ganessan Kichenadasse	SSA in progress	Pending	-
9	Chris O'Brien Lifehouse	NSW	John Simes	SSA in progress	Pending	-
10	Royal Hobart Hospital	TAS	Rosemary Harrup	HREC in progress	Pending	-
11	St George Hospital	NSW	Catherine Clark	SSA in progress	Pending	-
Total recruitment						5

VERTU (COGNO 14/01): Veliparib, Radiotherapy and Temozolomide trial in Unmethylated MGMT Glioblastoma. 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)

The VERTU trial aims to recruit 120 patients across 18 sites. As of 26th May 2017, 167 patients have been registered for screening and 47 were enrolled into the trial. Recruitment has slowed down since beginning of this year and the Trial Management Committee is currently discussing how to ensure recruitment stays on track to allow successful completion of the trial.

A new version of the protocol has been approved on the 26th May 2017 by the central Human Research Ethics Committee.

This protocol amendment provides updates and clarifications based on trial experiences in the past 18 months. Version 3.0 (3rd April 2017) will be rolled out to the sites shortly and it will also be able to be accessed via the NHMRC CTC Trial Web page (<http://www.ctc.usyd.edu.au/>).

The VERTU Trial Coordinator is more than happy to provide any information that you may require on this study. Please email vertu@ctc.usyd.edu.au if you have any queries.

VERTU - PARTICIPATING SITE STATUS							
No	Site name	State	Principal Investigator	Site status	Site activation	# Patients registered	# Patients enrolled
1	Canberra Hospital	ACT	Ganesalingam Pranavan	Active	27-Feb-17	1	0
2	Royal North Shore Hospital	NSW	Helen Wheeler	Active	09-Nov-15	38	7
3	Westmead Hospital	NSW	Najmun Nahar	Not active	Jun-17	0	0
4	Chris O'Brien Lifehouse	NSW	John Simes	Active	26-Nov-15	12	5
5	Liverpool Hospital	NSW	Eng-Siew Koh	Active	21-Jan-16	20	8
6	St George Hospital	NSW	Tracey Dunlop	Not active	Jun-17	0	0
7	Gosford Hospital	NSW	Matthew Wong	Active	7-Jun-16	4	6
8	Royal Melbourne Hospital	VIC	Mark Rosenthal	Active	28-Oct-15	5	1
9	University Hospital Geelong	VIC	David Ashley	Active	21-Jan-16	11	4
10	Epworth Healthcare	VIC	Ross Jennens	Active	14-Dec-15	11	2
11	Monash Medical Centre	VIC	Ronnie Freilich	Active	11-Feb-16	5	0
12	Border Medical Oncology	VIC	Christopher Steer	Not active	Jun-17	0	0
13	Royal Brisbane and Women's Hospital	QLD	Zarnie Lwin	Active	09-Nov-15	22	9
14	Princess Alexandra Hospital	QLD	Matthew Foote	Active	5-Jul-16	13	2
15	Royal Adelaide Hospital	SA	Nimit Singhal	Active	24-Mar-16	14	1
16	Royal Hobart Hospital	TAS	Rosemary Harrup	Active	02-Dec-15	10	1
17	Launceston General Hospital	TAS	Stan Gauden	Active	12-Dec-16	1	1
Total recruitment						167	47

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

The CABARET team have been very busy since the main results of the CABARET study were published, working on further manuscripts. We are now happy to report that we have 2 additional CABARET papers recently published, with more on the way.

The **Part 2 results** *Continuing or ceasing bevacizumab beyond progression in recurrent glioblastoma: an exploratory randomized phase II trial* were published in *Neuro-Oncology Practice* (ePub: 25 May 2017). The paper can be located here: <https://doi.org/10.1093/nop/npw025>

The **Quality of Life** paper *Health-related quality of life outcomes from CABARET: a randomized phase 2 trial of carboplatin and bevacizumab in recurrent glioblastoma* has been published in *Journal of Neuro-Oncology* (ePub: 22 May 17). The paper can be located here: <http://dx.doi.org/10.1007/s11060-017-2479-8>

Congratulations to Dr Kathryn Field and all the co-authors on their dedication and hard work and to all those who were involved in the CABARET trial.

If you have any enquiries regarding the CABARET study please don't hesitate to contact the CABARET team by email cabaret@ctc.usyd.edu.au.



COGNO
COOPERATIVE TRIALS GROUP
FOR NEURO-ONCOLOGY

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Dr Eng-Siew Koh (Deputy Chair)
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CATNON (EORTC 26053-22054): Phase III trial on concurrent and adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma

As previously reported, recruitment for the CATNON study closed on 17 Sep 2015 with 751 patients randomised internationally (1407 registered), and 82 randomised in Australia (191 registered); this represents approximately 11% of total trial accrual and is a great contribution to the global effort.

As all of our patients are now off study treatment, we have completed interim closure of Australian pharmacies. Study coordinators should have received the Pharmacy Folders back from site pharmacists to be included with study archiving (when the time comes for this). Please do not hesitate to get in touch with any questions regarding this process, if you have any concerns.

During the follow-up phase, we ask that you continue to send visit CRFs and respond to EORTC queries in a timely manner and thank you for your ongoing support. The study team can be reached at catnon@ctc.usyd.edu.au.

CRF tip:

As a reminder and for any new Study Coordinators, the EORTC's requests for 'overdue' or 'missing' CRFs in instances where these CRFs have already been provided to the CTC can be confusing.

Just to clarify, if a CRF is provided and it is outside EORTC's theoretical timeline (for that patient for that visit), the EORTC's data program will view this CRF as missing. In these instances, the EORTC have requested that sites provide a blank CRF stating 'not done' (with the theoretical date and adding a note on the form to specify that the visit was not done in allowed interval and give the real date on which the visit was performed.) *This is in addition to* providing a completed CRF with the actual visit date and visit data.

We understand that this puts extra pressure on sites to differentiate between what forms are actually missing entirely from the EORTC and those that are just requiring an additional blank CRF to be provided as the visit was attended outside window. Your efforts are much appreciated. Should you have any questions, please don't hesitate to contact us.

Importantly, and to minimise queries going forward, please communicate to all team members that will be completing CRF entry for CATNON that the first thing to do before completing any CATNON CRF is to refer to the theoretical schedule. If the visit falls outside the theoretical visit window, provide a blank CRF stating 'not done within visit window' and note the actual date on which the visit was performed. Then, complete a second CRF for the visit using the actual visit date.

MEMBERSHIP UPDATE

COGNO now has 624 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).

NEW CONCEPTS/TRIALS IN DEVELOPMENT

DO YOU HAVE A NEW TRIAL CONCEPT? COGNO is always looking to develop new trials - from inception through to full protocol development and managing feasibility and operational issues. We aim to help progress and support development of important clinical trial questions. If you would like to propose a concept or have an amazing idea for a COGNO trial, please contact us on cogno@ctc.usyd.edu.au or call Candace Carter (COGNO Development Program Manager) on 02 9562 5092 . Candace and the team can assist you to develop and progress your idea or assist you with completion of the Trial Concept Outline form available at www.cogno.org.au (on the home page under 'Ideas and Concepts').

IDEAS GENERATION WORKSHOP

COGNO's fourth Ideas Generation Workshop was held on 19 May 2017 in Sydney, co-convened by Mustafa Khasraw, Zarnie Lwin and Kathryn Field with the able support of Candace Carter. Nine interesting concepts were presented and discussed, with further development required on some before progression to consideration by the COGNO Scientific Advisory Committee. A special thank you to Mustafa and Zarnie who have been co-convenors on all four of our very successful Ideas Generation Workshops, and are now handing over to the very capable Kathryn.



L-R Mustafa Khasraw,
Zarnie Lwin,
Kathryn Field,
Candace Carter

REMINDERS/ADDITIONAL INFORMATION

- 23-24 Oct 2017 - 10th COGNO ASM, Melbourne, Australia <http://www.cogno.org.au/>
- 29 - 31 Oct 2017 - 14th Meeting of Asian Society for Neuro Oncology (ASNO), Knowledge Capital Congr s Convention Center, Osaka, Japan, <http://www.asno2017.jp/>
- 13 - 15 Nov 2017 - 2017 COSA ASM, Sydney International Convention Centre, Australia <http://www.cosa2017.org/>
- 16 - 19 Nov 2017 - 2017 SNO Meeting, San Francisco, USA <http://www.soc-neuro-onc.org/2017-sno-meeting/>

UPDATE FROM THE QUALITY OF LIFE OFFICE

The Quality of Life (QOL) Office is funded by Cancer Australia to provide advice and support to members of the 13 National Cancer Cooperative Trials Groups (including members of COGNO) on assessing patient-reported outcomes (PROs) in cancer clinical trials. For further information visit <http://www.pocog.org.au/content.aspx?page=QOL>.



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