ALLG AUSTRALASIAN LEUKAEMIA & LYMPHOMA GROUP

Improving the treatment and the lives of patients with blood cancers through clinical trial research

AUSTRALASIAN LEUKAEMIA AND LYMPHOMA GROUP

Trials Newsletter No 4

September 2014

This newsletter is published approximately every two months and provides update information on the ALLG trial program. Other ALLG activities are covered in the general newsletter published three times a year. To see the latest issue click HERE.

ALLG Trial Centre

Note new address:

35 Elizabeth St
Richmond
Vic

For more trial information visit the Members area at the ALLG website

ALLG Trial Centre special issue

This special issue of the Trials Newsletter focuses on major changes occurring with the management of ALLG trials.

The ALLG Trial Centre is in the process of expanding considerably, with several new staff and a new structure being adopted . Trials previously coordinated by the Centre for Biostatistics and Clinical Trials at Peter MacCallum are in the process of transitioning to management at the ALLG Trial Centre. Meanwhile the Trial Centre and the Operations Unit have moved to new independent premises in Richmond in inner Melbourne.

Read about all of this and more in this special Trial Centre edition. For trial specific news scroll further down the page.....

Milestones

- **NHL15 RECRUITMENT SUSPENDED - TMC currently considering action**
- **BM06 activated in Australia**
- **NHL27 to close to accrual internationally late October 2014**
- **MM16 submitted to first HREC**

Expressions of Interest

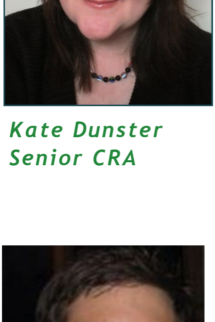
The ALLG Trial Centre is currently calling for Expressions of Interest for trial participation. Please reply to the survey registering your interest before the deadline to be considered.

Trial	PI	Contact person	Period for EOI
CML11 PINNACLE Phase II study of nilotinib plus pegylated interferon alfa-2b as first-line therapy in chronic phase CML aiming to maximize CMR and MMR	David Yeung, Tim Hughes, Andrew Grigg	Briony Tupper	places remaining
CLL7 An Australasian, phase II, multicentre, randomised, study investigating efficacy and safety for dose reduced fludarabine, cyclophosphamide and iv obinutuzumab (G-FC3) vs oral chlorambucil and iv obinutuzumab (G-Clb) in previously untreated, comorbid (CIRS score ≥6), elderly (≥65 years old) patients with CLL	Stephen Mulligan, Xavier Badoux, Con Tam	TBA	Expected to open to EOI Q4 2014
AMLM20 A programme of development for older patients with AML and high risk MDS	Andrew Wei	TBA	Expected to open to EOI Q1 2015

ALLG Trial Centre staff - who are they?

Megan Sanders
Program Manager

Megan's career has spanned the pharmaceutical industry, translational research and investigator-initiated clinical trials. She commenced in new product development at CSL, then went on to translational research with a PhD at the Department of Immunology, University of Melbourne. In her subsequent post doctoral position at The Ludwig Cancer Institute, Melbourne, she studied CD8+ T cell vaccines. Megan then returned to drug development and clinical trials, before commencing with the ALLG as the first Protocol Development Coordinator, where she coordinated the development of over 20 ALLG protocols spanning all disease areas. As Program Manager, Megan is responsible for establishing and managing the ALLG trial program including the ALLG Trial Centre.



Sarah Dewberry
Senior CRA

Sarah has been a CRA in the ALLG Trial Centre since its inception in July 2013. She has managed MM16 and BM06, and been responsible for preparing the SOPs for the ALLG Trial Centre. Prior to her appointment to the ALLG, Sarah held more senior positions in trial management and management of small teams at the Cancer Research UK Clinical Trials Unit at The University of Birmingham, and Leeds Institute for Clinical Trials Research in the UK. Sarah's experience in the practical application of GCP and good data management has been invaluable to the ALLG Trial Centre, and we have been delighted to appoint her as senior CRA where she can continue to pass on her knowledge to her team.

Kate Dunster
Senior CRA

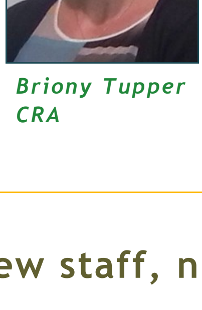
Kate has a background in flow cytometry in haematology but will be known to many of you from her position as Clinical Trial Manager in the Centre for Biostatistics and Clinical Trials at Peter MacCallum Cancer Centre, where she managed CML9. Kate has recently worked in data management at Biota in influenza vaccine trials but is keen to return to haematology and ALLG trials. Kate has experience in managing small teams during her career in laboratory haematology, and combined with her trial and data management experience, the ALLG has been pleased to appoint her as Senior CRA in the ALLG Trial Centre.

Andrew Budniak
CRA

Andrew had a successful career in business development for an eCRF company before deciding that he really wanted to work in clinical trial management. Andrew has previous experience as a Clinical Trial Associate at Leeds Institute for Clinical Trials Research in the UK, working primarily on trials in CLL. Andrew will commence as a CRA in the ALLG Trial Centre.

Sri Joshi
Data Manager

Sri has been appointed as data manager at the ALLG Trial Centre. Sri has most recently worked at INC Research as a clinical data associate, but has previously held more experienced posts in data management in Asia, including some time in investigator-initiated trials (IIT) in the Singapore Clinical Research Institute. Sri has expressed a keen desire to return to IIT, and displays a career history that shows he is always keen to tackle new projects. We are looking forward to Sri's integral role in rolling out the eCRF system and improving our data management procedures.



Bala Ravishankar
CRA

Bala has previous experience in drug development in India and then completed 11 months as a clinical trial manager at Biostatistics and Clinical Trials Department at Peter MacCallum Cancer Centre. Bala has previously worked on ALLG trials NHL25 and NHL21 at BaCT and now manages NHL27 and AMLM17, following his appointment as CRA in the ALLG Trial Centre in December 2013.

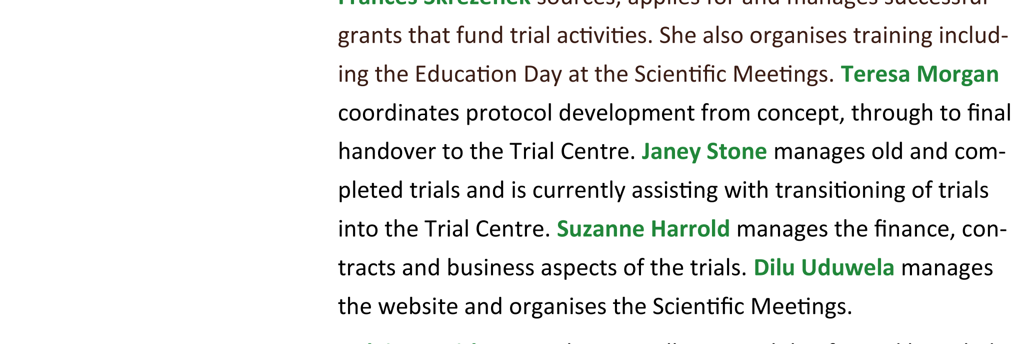
Briony Tupper
CRA

Briony has previous experience working in the Oncology Clinical Trials Office within the Department of Oncology at the University of Oxford, UK, coordinating multicentre trials in oncology. Prior to this, Briony worked in familial cancer research files in both colon and breast cancer studies at the Department of Epidemiology, University of Melbourne. Briony commenced at the ALLG in December 2013, and continues her CRA role managing NHL26 and CML11, and will be responsible for the first trial that moves to eCRF.

New staff, new structure

The ALLG Trial Centre staff will be grouped into small teams each with a Senior CRA and under the leadership of Program Manager Megan Sanders. In addition to the above appointments,, the ALLG will continue to recruit until sufficient positions are filled to accommodate the work of the Trial Centre including transition of trials from BaCT. Below is a schematic of the new structure.

We welcome the new members to our team in the ALLG Trial Centre and look forward to the exciting new phase in the ALLG trial program!



How the Operations Unit supports the Trial Centre

The Trial Centre carries out all the day to day trial management and coordination. But they couldn't do this without support from the team in the Operations Unit.

Frances Skrezenek sources, applies for and manages successful grants that fund trial activities. She also organises training including the Education Day at the Scientific Meetings. **Teresa Morgan** coordinates protocol development from concept, through to final handover to the Trial Centre. **Janey Stone** manages old and completed trials and is currently assisting with transitioning of trials into the Trial Centre. **Suzanne Harrold** manages the finance, contracts and business aspects of the trials. **Dilu Uduwela** manages the website and organises the Scientific Meetings.

Delaine Smith as CEO has overall responsibility for and knowledge of the entire trial program inclusive of the ALLG's business and operations.

Together the Trial Centre and the Operations Unit form a team dedicated to running and supporting the whole ALLG trial program.

Trials news

Acute Leukaemia/MDS Disease Group

AML/MDS Disease Group Chair
Andrew Wei

Exciting changes are underway for the **AMLM18 Registry.** Initially established at the Alfred as a registry for AML, the basic concept has been extended. The project has been renamed the 'National Blood Cancer Registry' to reflect the inclusion of other diagnoses and the protocol has been amended.. During September work began to transition the current paper CRFs to a digitally based system of eCRFs, with the assistance of specialist consultants. While this is occurring, the management of the Registry will be transferred to the ALLG Trial Centre. Streamlining of data management and logistics will be a priority.

All participating sites will be kept informed of changes throughout the process. For the present, please continue to direct any queries to Nola Kennedy.

The eCRF is expected to be available to sites by early next year. More details in the next newsletter!

AMLM17
CI: Andrew Wei
CRA: Bala Ravishankar ALLG Trial Centre

Cohort B of the phase I study with 50 mg lenalidomide and 12 mg/m^2 romidepsin is now open at two sites with two patients having been enrolled and screening underway for a third. If a dose limiting toxicity occurs in these patients, the cohort will expand to 6 patients. If none occurs, a higher dose cohort may be opened at the discretion of the TMC.

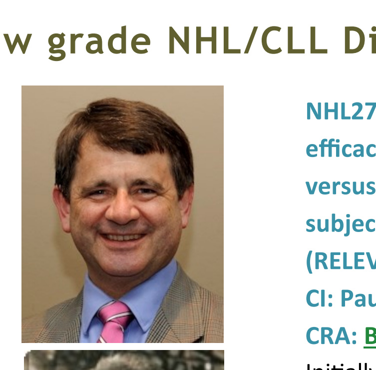
Multiple Myeloma

Multiple Myeloma Disease Group Chair
Peter Mollee

MM16 Phase II study assessing the effect of carfilzomib treatment on early free light chain kinetics in myeloma patients with renal impairment
CIs: Joy Ho, Doug Joshua
CRA: Sarah Dewberry ALLG Trial Centre

This trial has now been submitted for HREC approval as part of the National Mutual Acceptance scheme. It is expected to open to accrual in early 2015. Five sites will be running the trial and the ALLG very much encourages cross referral. Participating sites are RPA, Alfred, Royal Adelaide, Calvary Mater Newcastle and Princess Alexandra.

CML/Myeloproliferative Disease Group



CML/MPN Disease Group Chairs: Con Tam, Tim Hughes

CML11 PINNACLE Phase II study of nilotinib plus pegylated interferon alfa-2b as first-line therapy in chronic phase CML aiming to maximize CMR and MMR .
CIs: David Yeung, Tim Hughes, Andrew Grigg.
CRA: Briony Tupper, ALLG Trial Centre

There are still places available for sites to participate in this trial. If your site is interested please contact Briony. This will be one of the first trials to transition to eCRFs, and this is expected to occur early in 2015.

CML10 TKI Registry
CRA: Bronwen Ortlepp

Recruitment to Registries continues with accrual as of 1 September in the TKI Registry at 582 and the STOP Registry at 106. Recruitment to the correlative studies (currently 64) is on hold due to achievement of the recruitment target. However the Protocol Version 4 was approved by the SDMC on 25 August. This will re-open the correlative studies to enable recruitment of patients having a 'trial of cessation' (TOC) or progression to blast crisis, to a maximum of 50 patients having a TOC. If you have a patient who is to commence a TOC and protocol amendment 4 is not yet approved at your site, please contact Bronwen for an exemption to allow the patient to be enrolled into the correlative studies.

Low grade NHL/CLL Disease Group

NHL/CLL Chairs Stephen Mulligan, Campbell Tiley

NHL27 A phase 3 open-label randomized study to compare the efficacy and safety of rituximab plus lenalidomide (CC-5013) versus rituximab plus chemotherapy followed by rituximab in subject with previously untreated follicular lymphoma (RELEVANCE)
CI: Pauline Warburton
CRA: Bala Ravishankar, ALLG Trial Centre

Initially planned to run at 10 sites in Australia, international accrual rate for this trial was quicker than expected, and the trial will close to accrual in late October 2014. As a result only Wollongong, Concord and Nepean will be activated. We thank all interested sites for their efforts, and particularly Concord for the work with the NMA HREC submission.

CLL6
Cis: David Gottlieb, Con Tam

It is exciting to announce that ALLG have officially opened the CLL6 trial in 15 sites in France, and it is anticipated that a further 25 sites will join. This is an exciting time to be part of the CLL6 trial as it is the first native ALLG trial to be launched globally. Let's not forget also, the current 22 Australian participating sites actively accruing patients to this trial. Well done to all!

NHL16
CI: John Seymour

The SDMC and SAC have approved the recent amendment to extend the follow-up period for two years. The justification of the extension of follow-up is the exceptional results at 4 and 6 years in terms of PFS and lack of toxicity. Further follow-up would extend these findings and allow additional data on safety and late toxicity to be collected including second malignancies.

Documents to submit the amended protocol to site ethics committees are currently being sent out. In addition, this will be the first trial to commence transition from BaCT to the ALLG Trial Centre. During the transition phase, the trial will be managed by Janey Stone with assistance from Bereha Khodr.

BMT Disease Group

BMT DG Chairs David Ritchie, Ian Lewis

BM06 Phase III Clinical Study of Allogeneic Stem Cell Transplantation with Reduced Conditioning (RICT) versus Best Standard of Care in Acute Myeloid Leukemia (AML) in First CR
CI: David Ritchie
CRA: Sarah Dewberry, ALLG Trial Centre

Two sites in New Zealand, Wellington and Christchurch, will open an amended version of the protocol in the near future. The main feature of the amendment is to decrease SAE reporting for sites. Christchurch have already been running the trial functioning directly with the international coordinators in Sweden. They will now come under ALLG sponsorship as will Wellington.

This newsletter was edited by Janey Stone and approved by Delaine Smith and Megan Sanders.

Questions or comments? E-mail us at info@allg.org.au