

## Innovations: new trial seed funding scheme

Dear Colleagues,

It is with great pleasure that I announce the ALLG's new funding opportunity in support of our clinical trial program. The Board have approved the use of a discretionary amount of funding explicitly to seed fund new trials that are of scientific priority but may be experiencing difficulty with sourcing the initial funds to get started. The ALLG SAC have determined that the best process for review of project proposals for possible funding will be via the Disease Group Committee structure. I encourage you to read the guideline, which outlines clearly the intent and nature under which funds will be allocated. I also invite you to contact the respective DGC Chairs for further assistance and advice.

**Mark Hertzberg, Chair SAC**

For more information on the scheme see page 3.



## Learn to design a trial

### Australia & Asia Pacific Clinical Oncology Research Development Workshop (ACORD)

The ALLG is now a formal Sponsor of the ACORD workshop, and is delighted to offer an ALLG Member a scholarship to attend the ACORD Workshop held on the Sunshine Coast, 9-15 September 2012.

The Workshop is a week-long intensive training program which focuses on the essentials of clinical trials design in oncology research.

The Workshop is delivered through lectures, small group discussions and one-on-one mentoring and participants receive individualised assistance with

the protocols they have selected to develop. A call for expressions of interest from the membership will be made in January. For more information on the scholarship contact [Melissa Benedict](#).



The ALLG newsletter is published quarterly. It is designed and edited by **Janey Stone** and authorised by **Delaine Smith**.

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## Inaugural CEO, Delaine Smith!!

The ALLG Board is proud to announce the appointment of Delaine Smith to the position of Chief Executive Officer. The evolution of the group necessitates a more formal corporate management. The new CEO will role will:

- Provide leadership and oversight to the business and operations of the ALLG.
- Broaden and strengthen the ALLG sphere of influence and collaboration both nationally and internationally.
- Improve the clinical trial research capabilities for the members via a sustainable clinical trial program. Boost support from the community, sponsors, funders and partners.

**Please join me in congratulating Delaine as we welcome her to the challenging new role of CEO.**

*Peter Kempen Chairman of the Board*

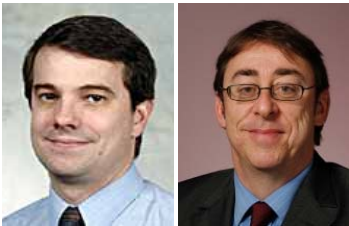
**ALLG Board**

**Independent members**

Peter Kempen - Chair  
 Geraldine Gray  
 Malcolm McComas  
 John Mortimore

**ALLG members:**

Mark Hertzberg  
 (Chair SAC)  
 Peter Bardy  
 Andrew Roberts  
 Andrew Spencer



**Board matters**

The Board has established a marketing committee to commence, deliver and continue the much needed promotion of the organisation. Despite our current limited resources, we are dedicated to a range of strategies:

**Increase awareness about the ALLG**

- General Public Awareness: The ALLG will produce brochures and literature to support site staff as the public face of the ALLG, make improvements to the website specific for public use and promote the ALLG in appropriate media e.g. newspapers.
- Health service awareness: education and training materials, etc., to enhance the ALLG profile (capability, role and responsibility in clinical trial conduct) to hospitals staff, clinician members, medical practitioners, nurse and allied health professionals.

**Strengthen the existing linkages** with other national and international cooperative trials groups, through personal representation at meetings and on committees, to be greater involved in information exchange and corporate dialogue.

**Approach Government and key non-government organisations** to promote the vital role and funding requirements of the clinical trial program.

**Broaden the membership categories** to capture the highest possible involvement of health professionals and the public in the group.

**Develop the fundraising message** to key target markets and use the so-called “social media” in a proper and meaningful fashion to communicate directly with our potential supporters.

Substantial work has been undertaken to establish the fundamental plans. The first priority is to the develop materials that have a uniform approach to delivering the message about the ALLG’s clinical trial research program.

The members of the Marketing committee are: John Mortimore, Geraldine Gray, Anne Hodgson, Sandra Slater, and ALLG office staff Dilu, Melissa and Delaine.

Please contact [Dilu](#) if you would like further information or have an idea to contribute.

**Funding the Tissue Bank - a Board priority**

The Board has taken up the issue of funding of the Tissue Bank as a major priority. It has been essential to tackle the concerns in light of the end of the NHMRC enabling grant funding next March.

Established by the ALLG in 2006, the National Leukaemia and Lymphoma Tissue Bank received an initial government Infrastructure Enabling Grant from the National Health and Medical Research Council (NHMRC) which formally ended in 2010. We have been fortunate to receive extension funding until March 2012. However, changes in the NHMRC’s funding policy will draw away the Tissue Bank’s main source of future funds and threaten the existence of this

precious resource. Despite our efforts to secure some capacity of philanthropic support, there is still considerable need for the Government to corroborate in this national effort.

The Board have invited Minister Butler to address the opening of the November Scientific Meeting. In so doing, we’ve requested the Minister to clarify the Government’s position in relation to funding the substantial infrastructure required for clinical research, and how this aligns with the vision for future health outcomes for the Australian population.



**The Hon Mark Butler MP**  
 Minister for Mental Health and Ageing  
 Responsible for the NHMRC

**MISSION STATEMENT**

*To improve the treatment and the lives of patients with leukaemia, lymphoma and other haematological malignancies by advancing ‘leading edge’ clinical trials in Australasia, and to be regarded by the local and international community as the peak research body for these diseases within our geographical areas of operation and influence*

## Scientific Advisory Committee

The **Disease Group Committees** are establishing their programs and will meet twice a year at a minimum. In order to encourage involvement with the ALLG from the outset, newly joined members are now invited to join DGCs and increase their participation with the ALLG's clinical trial program. The SAC would like to have broad national representation in the DGC's, if you would like to know more please contact Dilu Uduwela.

The **Acute Leukaemia committee** is focussing on the common study entry process for AML proposed by Andrew Wei. There is potential to harmonise many of the patient processes, including registration, CRFs, tissue banking, follow-up etc. As Andrew himself emphasised, this is a challenging task and will require its own protocol. The **BMT group's** main activity is further developing the MAVRIC protocol and in particular identifying funding sources. The **CML group** are working on several ideas. CARNI has been renamed PINNACLE and it is hoped this will be developed in coming months. The **Laboratory Science Committee** is working on ways to ensure all trial protocols have lab studies incorporated and funded.

The **signs of the economic times** were clearer than ever following reports on reduced government financial support for clinical trials. The NHMRC addressed clinical trials at a workshop in June, at which Andrew Wei represented the ALLG. The government has committed \$2 mill for future infrastructure funding but plans have not yet been released. The ALLG has provided discussion paper feedback to four of the Clinical Trials Action Group (CTAG) recommendations relevant to NHMRC mandate, we are hopeful of further interactions over the coming months. Unfortunately too Cancer Australia, due to Federal funding cuts, has ended the Regional Boost Program initiative. This will affect trial staff EFT at seven ALLG sites and the effect ALLG trials in progress will be reviewed. The ALLG has approached Cancer Australia for assistance with leadership in the matter.

### A Kiwi for the SAC

Ken Romeril from Wellington Hospital has been coopted onto the SAC as representative from New Zealand on the SAC. Ken is an Otago graduate who trained in Christchurch and at St Vincent's in Sydney and Southampton, UK. He has been at Wellington Hospital since 1986 and also works at the Aotea Laboratory. Ken has been Chair of the NZ Leukaemia Study Group and was also chair of the joint college committee that oversees registrars' training. Ken has particular interests in myeloma cytogenetics and novel therapies and is a PI in a number of trials in myeloma and lymphoma. You can see Ken's photo at right, just above John Seymour.



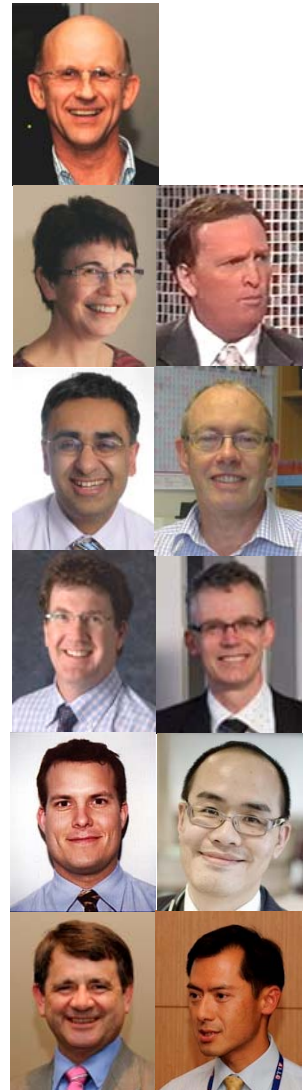
### From little things - seed funding guidelines

The Board approved a program to seed fund ALLG clinical trial research, and have delegated the decision making and processes to the SAC.

The intention of discretionary funding is to support the ALLG clinical trial program. Advancing the ALLG reputation locally and in the international research arena is a priority for the ALLG. A single project may be more appropriate to fund as opposed to multiple small proposals, and this will be determined at the discretion of the SAC. Utilisation of seed funding will allow the SAC to support timely and continuous research work. The process will operate via the Disease Groups with each committee reviewing its own projects first. As this is seed funding, the applicant will need to provide details of where other funding sources are being pursued and an expected timeframe. PIs of proposed studies will **submit their proposal** to the DGC Chair. Discussion will then revolve around issues such as:

- Scientific **validity** and viability of proposal
- Other clinical trial or project funding in place/secure
- The plans for acquisition of **alternate funds**
- Likelihood of securing remainder of trial **budget** funds
- **Timeframe** for project conduct
- Timeframe for funding
- **Risk assessment** of project success/failure to recoup seed funds

DGC Chairs will then submit their preferred application to the SAC for decision. Please contact the respective DGC Chair or ALLG office for further information.



#### SAC members

- Mark Hertzberg (Chair)
- Pauline Warburton (Vice Chair)
- Maher Gandhi (coopted)
- Ian Lewis
- Tony Mills
- Stephen Mulligan
- David Ritchie
- Ken Romeril (coopted)
- John Seymour
- Con Tam
- Andrew Wei



Funded by



Australian Government

National Health and Medical Research Council

A Partnership of



## ALLG Tissue Bank

### Sample coordinator - Jana Dracopoulos

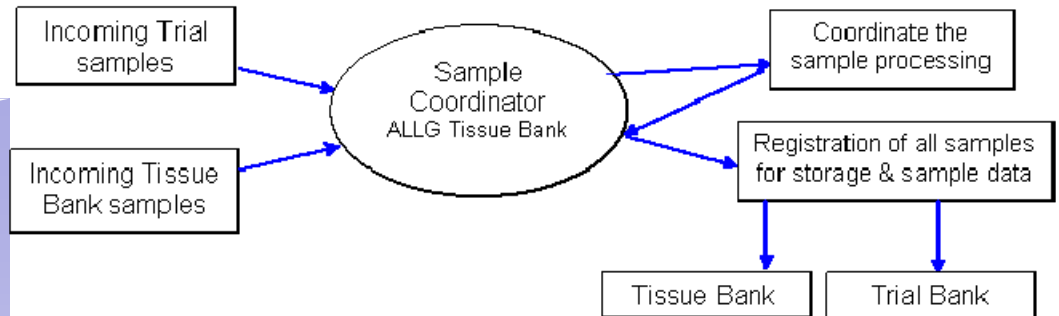
As the Tissue Bank's sample coordinator Jana Dracopoulos has her hands full. In a nutshell her main role involves two directions – samples coming in, and samples going out. Easy-peasy you think? Well consider.

On the samples-in side, Jana coordinates the trial and/or tissue bank sample uptake, sometimes with processing, of 20 trials (15 ALLG, 5 non-ALLG) as well as uptake of all non-trial patients samples collected from the 26 sites with the generic Tissue Bank consent

The samples-out side has two components. For laboratory research projects, Jana performs searches of the Tissue Bank holdings for suitable samples and coordinate the extraction and dispatch of selected tissue bank samples to approved researchers. And for trials, coordinates dispatch of trial samples to the nominated correlative testing laboratories.



Jana sits in front of the Great Wall of Trials



**CONTACT INFORMATION**  
 General email address:  
[allg\\_tissue\\_bank@health.qld.gov.au](mailto:allg_tissue_bank@health.qld.gov.au)

Sample Coordinator  
[samplecooordallgtissue-bank@health.qld.gov.au](mailto:samplecooordallgtissue-bank@health.qld.gov.au)  
 STAFF

Ms Megan Ellis  
 ALLG Tissue Bank Manager  
 07-3176 5835

Dr Lyle McMillen  
 Research Scientist  
 07-3176 5464

Ms Jana Dracopoulos  
 Sample Coordinator  
 07-3176 5838 or  
 3176 5836

Mrs Josie Thomas  
 Laboratory Scientist  
 07-3176 5839

Postal address for samples

**Attention:**  
 Staff of the ALLG Tissue Bank  
 Princess Alexandra Hospital  
 c/- Haematology/Pathology,  
 Main building level 1  
 Ipswich Road  
 Woolloongabba Qld 4102

### Publications based on Tissue Bank samples 2011

M Green, C Aya-Bonilla, M Gandhi, R Lea, J Wellwood, P Wood, P Marlton and L Griffiths. Integrative Genomic Profiling Reveals Conserved Genetic Mechanisms for Tumorigenesis in Common Entities of Non-Hodgkin's Lymphoma. *Genes, Chromosomes & Cancer* 50:313–326, 2011

M. Lutherborrow, A. Bryant, V.Jayaswal, D.Agapiou, C.Palma, Y.Yang, D.Ma.Expression profiling of cytogenetically normal AML identifies microRNAs that target genes involved in monocytic differentiation. *American Journal of Haematology*, 86:2-11, 2010 (note correct year)

### Translational News - MM6 Proteomics study

The aim of this study is to risk-stratify patients and identify biomarkers that predict for response to thalidomide by using a panel of proteomic immunohistochemical (IHC) antibodies. Previous work published by the Myeloma Research Group, Alfred Hospital (Dawson et al. 2009) has investigated a range of IHC biomarkers known to have a fundamental role in the pathogenesis of MM (including those of cell cycle activity, apoptosis and angiogenesis) in predicting outcome to bortezomib therapy.

The Alfred Trial Centre are now asking sites with patients who signed the additional consent to start preparing samples to send to them for analysis. Myeloma fellow, Dr Anna Kalff is coordinating this project. Please contact her on 03-9076 5406 or at [a.kalff@alfred.org.au](mailto:a.kalff@alfred.org.au) with any queries

## Trial News

### Trials under development

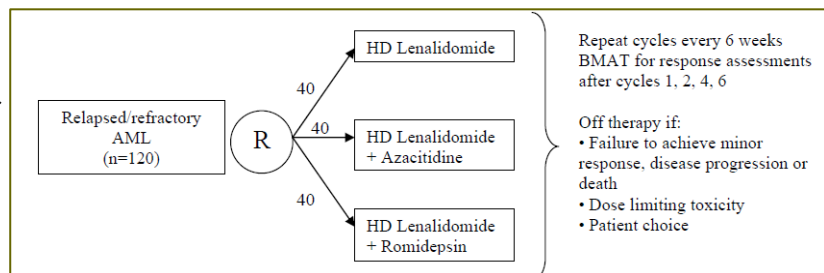
#### AML M17 PI: Andrew Wei

##### *A Strategy of High-Dose Lenalidomide in Combination with Epigenetic Therapies for Relapsed and Refractory Acute Myeloid Leukaemia*

Treatment options are limited for patients with advanced AML who **fail to respond, or who progress after treatment** with chemotherapy or hypomethylating agents. Fifty percent of AML patients under the age of 60 and the majority of older patients will relapse despite attaining initial remission with intensive chemotherapy. For 82% of adult patients, the length of the second remission after salvage chemotherapy is less than 3 months. Novel

therapeutic options are urgently needed in this population. At present, the safety and tolerability of high dose (HD) lenalidomide with HiDAC therapy is unknown. AML M17 aims to explore the potential for HD lenalidomide in combination with epigenetic therapies, to improve clinical outcome in advanced AML, including patients previously treated with hypomethylating agents.

To allow some preliminary comparisons between therapeutic options to be made, **a three way randomisation** between HD lenalidomide alone, or in combination with epigenetic therapies (azacitidine or romidepsin) is being considered. The initial stage of the study will look at a smaller number of patients to investigate the appropriate dose for the combination of romidepsin and lenalidomide. Once this has been established, the study will investigate, in a second stage, the efficacy of two novel treatments (HD lenalidomide + azacitidine and HD lenalidomide + romidepsin) compared with a control treatment (HD lenalidomide alone), in patients with relapsed or refractory AML, as measured by the complete remission (CR or CRi) rate following two cycles of therapy. Target accrual is 120 patients over 30 months. Refinement of the design will occur over the coming months



#### AML M18 PI: Andrew Wei

##### *ALLG Common AML Registry*

Currently, the ALLG has several studies which involve molecular profiling as part of the selection criteria. AML M15 and AML M16 require pre-screening of FLT3-ITD mutation to determine patients' eligibility to participate in either clinical trial.

The aim of this project is to establish a platform consisting of AML patients among participating ALLG sites as part of the pre-screening process for AML M15 and AML M16 studies, that is, quicker and easier entry. This will also allow the integration of data from AML patients not participating in trials. The goal is to gain a better understanding of disease progression and pattern of care for AML patients not participating in a clinical trial and to inform and facilitate design of future ALLG AML studies.

The rationale for this includes:

- Avoidance of patients having to sign more than one consent form at diagnosis
- A mechanism that will allow the modular activation and deactivation of AML studies over time
- A mechanism that will allow cross-referral of registered patients to another institution without needing patients to have procedures duplicated
- Improved collection of clinical data of tissue banked samples, especially at time of relapse and for patients not on an active AML study
- Greater central review of cytogenetic data
- A large clinical AML database in ANZ, to inform current practice and future trial design
- A desire to facilitate conduct of laboratory based studies in AML without disrupting existing trials

**The Registry will be launched at the November meeting and there will be plenty of further information available coming** Page 5



**AML M17 and  
AML M18 PI:  
Andrew Wei**

## Trial News

### New trials



#### **AMLMI5 PI: Andrew Wei**

##### *A pilot study exploring high-dose lenalidomide maintenance therapy in adult AML*

##### **Trial Manager: Gemma Tait.**

This pilot study has accrued five patients at three sites already since it opened in September. Target accrual is 30-50. Currently activated are the Alfred Hospital, Queen Elizabeth and Calvary Mater Newcastle, with up to 13 sites expected to participate. Responsibility for this trial has recently been taken over by a new trial manager at BaCT, Gemma Tait (see her bio on page 16).

An amendment was approved by the SDMC in July. It comprised a number of small modifications that will enable study entry and registration procedures to occur without compromising the collection of vital trial data. The main effect was to clarify the wording of the inclusion criterion at registration prior to induction chemotherapy so that the registration procedure will not be compromised by the possible time delay for results to be reported as per the WHO criteria. This relaxes the timing but still ensures immunophenotyping is confirmed and reported for each study participant.



**AMLMI5, MI6  
PI: Andrew Wei  
Trial Manager:  
Gemma Tait**

#### **AMLMI6 PI: Andrew Wei**

##### *Sorafenib in combination with intensive chemotherapy for previously untreated adult FLT3-ITD positive AML: a phase 2 randomised placebo controlled multi-centre study*

##### **Trial Manager: Gemma Tait**

Despite intensive chemotherapy, the survival of patients with AML bearing FLT3 mutation (25% cases) is poor. The reason for this is that the FLT3 mutation confers resistance of leukaemic cells to therapy, resulting in early disease recurrence.

This study will evaluate in a randomised study the ability of an FLT3 inhibitor (Sorafenib) to neutralize the effects of mutant FLT3 when administered with intensive chemotherapy. This study will determine the clinical benefits of this approach in the context of a national Australian study and also search for molecular predictors of response.

The AMLMI6 protocol has just obtained approval from the ALLG SDMC on the 10 October, and it is about to be handed over to the Trial Centre. This means you can expect to see a call for expression of interest in your Inbox in the near future.



**ALL6 PI: Ken Bradstock  
Trial Manager: Lavanya Gupta**

#### **ALL6 PI: Ken Bradstock**

##### *A phase II trial of an intensive pediatric protocol incorporating post-induction stratification based on minimal residual disease levels for the treatment of adolescents aged 15 years and above, and young adults aged up to 40 years, with newly diagnosed acute lymphoblastic leukaemia (ALL)*

##### **Trial Manager: Lavanya Gupta**

With 49 sites having initially expressed interest, this trial may well be bigger than Ben Hur, although it is anticipated that only 15 will actually participate. Other sites will be able to refer patients to participating centres. This will be the first trial of the group specifically targetted to the adolescent/young adult age group, and thus it charts a new direction for the group. The SDMC approved the protocol in July and the trial has been handed over to the Trial Centre at BaCT, who are currently receiving site EOIs and setting the trial up. It is anticipated that ethics submissions will be completed soon and the trial will open to accrual by the end of the year

## Can you TOP this?

**PIs: Kate Stern, Andrew Grigg**

*A randomized controlled trial evaluating the protective effect of a gonadotrophin-releasing hormone agonist on ovarian function in young women with Non-Hodgkin's Lymphoma receiving R-CHOP-14*

**Melbourne IVF** is leading a national, multi-centre, investigator-initiated, randomised controlled trial, evaluating the protective effect of a GnRH agonist (GnRH-a) on ovarian function in young women with NHL receiving R-CHOP-14 at risk of ovarian failure and infertility. Advances in chemotherapy regimens have seen survival rates for NHL patients exceed 90%. For these young women, attention is increasingly drawn to the risk of ovarian failure as a consequence of treatment.

There is evidence that **GnRH-a may protect the ovaries during chemotherapy** and thus reduce the risk of premature menopause and infertility. This trial aims to assess whether a GnRH-a given during a fixed chemotherapy protocol for NHL can protect ovarian function and potential fertility. Patients are randomised to receive chemotherapy and either a progesterone-only oral contraceptive pill or a progesterone-only oral contraceptive pill plus GnRH-a. Assessment consists of blood tests, bone density tests and ultrasound over 5 years, with primary endpoints measured at 12 months and 3 years.

Despite increased longevity of cancer survivors, approaches to improving their quality of life are not well-understood. This is of particular importance for young female survivors, where **preserving ovarian function**, either for the purpose of fertility preservation or for restoration of endocrine function, is a concern. The lack of rigor of trials evaluating GnRH analogues in this setting, with only one published randomized controlled trial in breast cancer patients, highlights the need for further properly conducted studies. This study will aim to provide evidence-based practice for clinicians and increased options for this population of women.

The trial is open for recruitment and seeks women aged 14 - 38 who are anticipated to receive 6 cycles of R-CHOP-q14 chemotherapy treatment, with curative intent for NHL

### How can you help?

Patients can be referred to the doctors at the below centres for discussion about the fertility implications of their cancer treatment (including access to the full range of fertility preserving options) and their interest in participating in the trial. **Haematologists will not be required to consent the patients as this will be done at the respective fertility centres.**

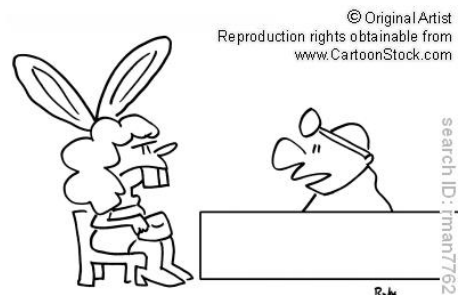
*This study will aim to provide evidence based practice for clinicians and increased options for this population of women.*

### Trial Contacts

**PI:** Kate Stern 03-9415 1838  
call service: 03-9387 1000  
**PI:** Andrew Grigg 03-9496 5093  
**Research staff:**  
Franca Agresta 03-9473 4570  
Tanya Stewart 03-9473 4569

### Participating fertility specialists and IVF units

<b>VICTORIA</b>	Dr Kate Stern, Melbourne IVF & Royal Women's Hosp
<b>NSW</b>	Dr Juliette Koch, IVF Australia, Sydney
<b>QLD</b>	Dr Ben Kroon, Queensland Fertility Group Dr Anusch Yazdani, Queensland Fertility Group
<b>WA</b>	Dr Roger Hart, Fertility Specialists of WA
<b>SA</b>	Dr Rob Norman, Fertility SA
<b>NEW ZEALAND</b>	Dr Mary Birdsall, Fertility Associates, Auckland



"I warned you that the fertility drugs might have side effects."

## Current trials

### MDS4 PI: Melita Kenealy

*A Randomised Phase II study comparing the efficacy of azacitidine alone versus combination therapy with lenalidomide and 5azacitidine in patients with higher risk myelodysplastic syndromes (MDS) and low marrow blast count acute myeloid leukaemia (AML)*

**Trial Managers: Linda Cowan, Ania Matera**

Opened August 2010, this trial wowed them from the start. The 25% accrual point has already been reached with 40 of the target of 160 accrued at the end of August 2011. Accrual is right on schedule. Keep up the good work and thanks to everyone who has supported the study.

We all like holidays, but this trial presents problems for azacitidine dosing on a public holiday. Linda has distributed detailed guidelines on what to do. Advice is included for D1 and D8 falling on a Monday public holiday for both 5-2-2 and for 5 day dosing, as well as for Melbourne Cup Day and Xmas holiday dosing.

Please note CID1 for any new patients should be scheduled to avoidance subsequent cycles dosing days falling on Xmas/NY public holiday. Please give Linda a heads up for existing pts if that might happen.

If at all possible, dosing should continue as scheduled, even if on weekend or on the public holiday (ie assuming clinic is open); Once reconstituted, azacitidine is stable for 1h at room temperature and 8h refrigerated. It is stable for 22h if reconstituted using "cold-water reconstitution" and refrigerated as per current Product Information (available on the ALLG Website).



**MDS4 Trial Managers:**  
Linda Cowan, Ania Matera

## Trial Milestones 2011

Further information on all trials is on the ALLG Website. For detailed information on current trials contact the Trial Manager ([page 17](#))

### Studies opened

MM13	A randomized open-label multicenter phase III trial of Melphalan and Dexamethasone (MDex) versus Bortezomib, Melphalan and Dexamethasone (BMDex) for untreated patients with systemic light-chain (AL) amyloidosis	Peter Mollee	approved by SDMC 14/2/2011
AMLM15	A pilot study exploring high-dose lenalidomide maintenance therapy in adult AML	Andrew Wei	
CLL6	An Australasian, Phase III, Multicentre, Randomised Trial Comparing Lenalidomide Consolidation Vs No Consolidation in Patients With Chronic Lymphocytic Leukaemia and Residual Disease Following Induction Chemotherapy	David Gottlieb, Con Tam	
ALL6	A Phase II trial of an intensive paediatric protocol incorporating post-induction stratification based on minimal disease levels for the treatment of adolescents aged 15years and above, and young adults aged up to 40 years, with newly diagnosed acute lymphoblastic leukaemia (ALL)	Ken Bradstock, Luciano Dalla Pozza	Approved by SDMC 25/7/11

### Studies closed to accrual

CML9	A Phase II study in adult patients with newly diagnosed chronic-phase chronic myeloid leukaemia of initial intensified imatinib therapy and sequential dose-escalation followed by treatment with nilotinib in suboptimal responders	Tim Hughes	closed to accrual 25/3/2011 - reached target
AMLM14	A trial for older patients with acute myeloid leukaemia and high risk myelodysplastic syndrome (NCRI AML16)	Andrew Wei	closed to accrual 8/4/2011 - reached international target
MM11	A Phase 3, Multicentre randomised controlled study to determine the efficacy and safety of Cyclophosphamide, Lenalidomide and Dexamethasone (CRD) versus Melphalan (200mg/m <sup>2</sup> ) followed by Stem Cell Transplant in newly diagnosed Multiple Myeloma subjects	Andrew Spencer	closed to accrual 6/5/2011 - reached accrual
CML8	A phase II study of withdrawal of imatinib therapy in adult patients with chronic phase chronic myeloid leukaemia in stable molecular remission	Tim Hughes	closed to accrual 28/7/2011 - reached target accrual

## Featured trial - having a PET is positive!

**NHL21 PIs: Mark Hertzberg, Rod Hicks**

*Early treatment intensification with R-ICE chemotherapy followed by autologous stem cell transplantation using Z-BEAM for patients with poor prognosis diffuse large B-cell lymphoma as identified by interim PET/CT scan performed after four cycles of R-CHOP-14 chemotherapy*

**Trial Manager: Ruth Columbus**

**Current Version: Version 6 dated 02 September 2011**

### Trial update

With patient accrual at more than 90 we have established a PET-positive rate of approximately 22%, a value in alignment with other similar studies. The plan now is to increase the sample to ensure achievement of the primary objective, which is to demonstrate an absolute improvement of 25% in two-year progression-free survival from 20% to 45% in those patients with advanced stage DLBCL who have been identified with a positive interim-treatment PET/CT scan. The amendment to increase the sample size will be distributed in mid-October.

### Your FAQ's answered:

#### Which patients are eligible?

Any high-risk DLBCL patient with stage III/IV disease, raised LDH and less than 65-70 yrs is eligible and should be enrolled onto this study. The inclusion criteria allows patients with IPI of >2 or higher, or IPI < 2 with bulky disease.

#### Which patients go to salvage?

Only patients with a positive interim PET/CT scan at cycle 4 R-CHOP (compared to cycle 2 in other studies) will go onto salvage with RICE and Z-BEAM. This delay in interim PET to cycle 4 improves the positive predictive value of the interim PET and provides more certainty around the intervention.

See the table below of recent studies showing poor PFS for those who are PET positive at cycle 4 R-CHOP.

#### Which patients can access Zevalin?

The trial offers access to Zevalin in conditioning for those with a positive interim PET scan.

#### Are there any safety concerns?

Intensive high dose therapy in 1st line treatment has been used in very recent trials among DLBCL patients including:

- 3 consecutive autografts in the German randomised Mega-CHOEP study reported at ASH 2010 and ICML 2011.
- An upfront autograft in the large randomised SWOG study reported at ASCO last month (*Stiff et al J Clin Oncol 29: 2011 suppl; abstr 8001*)
- An autograft if PET positive at cycle 2 in the large GELA randomised study reported in Blood in August.

Recent studies indicate the merit of this approach in DLBCL and reinforce the scientific value and critical need for Australia's corroboration in this research effort. Please contact Mark Hertzberg or Rod Hicks if you have questions about the positive predictive value of interim PET.



**PIs: Rod Hicks, Mark Hertzberg**

Author	Timing of interim PET	PFS 2yrs	PFS 2 yrs	Reference
	Scan cycle#	Positive	Negative	
Dupuis '09	PET#4	36% 5 yr	80% 5 yr	Ann Oncol 2009
Safar '09	PET#4	47%	81%	ASH 2009
Itti '09	PET#4	25%	82%	J Nucl Med 2009
	PET#4	38%	82%	J Nucl Med 2009
Itti '10	PET#4	52%	82%	J Nucl Med 2010

## Closed trials

### It's cleanup time!

Do you find those constant requests to clarify trial data difficult to keep up with? Perhaps you're wondering what all the fuss is about? As we all know, trial results are only as good as the quality of the data. As much as we all are impatient for the analysis and results once a trial has closed, the statisticians can't begin their work until the data is clean.

And often there are major deadlines - abstract submissions and protocol specified interim analyses for instance. Below is a list of the trials currently undergoing cleaning and being readied for key analyses in BaCT. So when you get your data clarification request you will understand why it's important that replies need to be prompt and accurate.

The urgent ones are highlighted in the colour of blood - to help you remember to provide an injection of DCSF (Data Collection Stimulating Factor)!



We want you to...  
 Send in your CRFs  
 NOW!!!

Inject DCSF  
 (Data Collection Stimulating  
 Factor) HERE

Trial	Current activities	Purpose and deadline
ALL3	Updating previous report of final analysis of survival and response.	Preparation of manuscript. Final report to be updated by Sept 2011.
AML12	Palifermin data cleaning and analysis to be completed. This analysis to see if palifermin can be used as a potential means to reduce the mucosal toxicity of chemotherapy for AML.	Palifermin data analysis planned for 3rd quarter of 2011.
AML12	This trial has a large number of patients and data cleaning continues on all patients	Main analysis planned for 2013.
<b>AML13</b>	<b>Data cleaning needs to be completed urgently</b>	<b>Main analysis for response, survival, and correlative markers is in progress.</b>
APML4	Data cleaning continues	Final analysis planned for 2012
CML6	Data cleaning continues.	Final analysis planned for end 2011
CML8	Data cleaning of the baseline data to be completed by Oct 2011	Baseline Data Analysis planned for Nov 2011.
CML9	Data cleaning and analysis for Cohort 1 (12 mth) completed.	Manuscript submitted
CML9	Data cleaning continues for Cohort 1 (24 mth) response analysis.	Analysis planned for 2012
CML9	Data cleaning started for cohort 2 (12 mth) response analysis.	Analysis planned for 2012
MDS3	Data cleaning for main analysis to be completed urgently	Preparation of manuscript and main analysis is in progress
MDS3	Data cleaning to continue for QOL	QOL analysis (Timeline TBA).
NHL11	Data cleaning continues	Final analysis planned for Q3 2011

### MM6 PI: Andrew Spencer

*A Phase 3, Multicentre, Randomized, Controlled Study to Determine the Efficacy and Safety of Cyclophosphamide, Lenalidomide and Dexamethasone (CRD) versus Melphalan (200mg/m<sup>2</sup>) Followed by Stem Cell Transplant in Newly Diagnosed Multiple Myeloma Subjects*

#### Trial Manager: Nola Kennedy

We currently are collecting outcome data in order to perform a third and final analysis of the ALLG MM6 study. Whether or not there is a survival benefit for maintenance /consolidation thalidomide remains unclear with only two groups reporting longer-term follow-up, with conflicting results (Attal et al. 2006; Barlogie et al. 2008). The long-term analyses of clinical outcomes for the MM6 study at a later closeout date will make a significant contribution to the literature/patient management (minimum follow-up 54 months).

Also being collected is response to first post relapse therapy and secondary primary malignancy, following concerns raised at ASH (December 2010) and IMW (May 2011), regarding secondary malignancies being diagnosed after treatment of multiple myeloma. The IFM-2005-02 study of maintenance lenalidomide in patients with MM post-ASCT found an increase in the incidence of both haematologic and non-haematologic malignancies at a median follow-up of 34 months post randomisation. For these reasons it is essential that the outstanding data be sent in as soon as possible. For any queries contact [Nola Kennedy](#) or [Anna Kalf](#).



MM6 PI  
 Andrew Spencer

## Current Trial Manager Contact List

*For up-to-date information including accrual and all essential documents go to the ALLG website.*

<b>Trial</b>	<b>Status</b>	<b>Trial Manager</b>	<b>Location</b>	<b>Email</b>	<b>Phone No</b>
ALL5	Open	Juliana Di Iulio	BaCT	Juliana.Dilulio@petermac.org	03-9656 3786
ALL6	Set-Up	Lavanya Gupta	BaCT	Lavanya.Gupta@petermac.org	03-9656 5807
ALL7	Open	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
AMLM12	Follow-up	Juliana Di Iulio	BaCT	Juliana.Dilulio@petermac.org	03-9656 3786
AMLM13	Follow-up	Teresa Morgan	BaCT	Juliana.Dilulio@petermac.org	03-9656 3786
AMLM14	Follow-up	Lavanya Gupta	BaCT	Lavanya.Gupta@petermac.org	03-9656 5807
AMLM15	Open	Gemma Tait	BaCT	Gemma.Tait@petermac.org	03-9656 5289
AMLM16	Devlop	Gemma Tait	BaCT	Gemma.Tait@petermac.org	03-9656 5289
APML4	Follow-up	Juliana Di Iulio	BaCT	Juliana.Dilulio@petermac.org	03-9656 3786
BM07	Open	Ania Matera	BaCT	Ania.Matera@petermac.org	03-9656 3661
CLL5	Open	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
CLL6	Open	Thao Le	BaCT	Thao.Le@petermac.org	03-9656 5268
CML4	Analysis	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
CML6 (ext study)	Continuing	Ruth Columbus	BaCT	Ruth.Columbus@petermac.org	03-9656 5827
CML7	Analysis	Michael Kornhauser	BaCT	Michael.Kornhauser@petermac.org	03-9656 5288
CML8	Follow-up	Michael Kornhauser	BaCT	Michael.Kornhauser@petermac.org	03-9656 5288
CML9	Follow-up	Michael Kornhauser	BaCT	Michael.Kornhauser@petermac.org	03-9656 5288
CML10	Open	Bronwyn Cox	Royal Adelaide	Bronwen.Cox@health.sa.gov.au	08-8222 3368
HDNHL4	Follow-up	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
HD04	Follow-up	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
HD08	Open	Lavanya Gupta	BaCT	Lavanya.Gupta@petermac.org	03-9656 5807
LY03	Follow-up	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
MDS3	Analysis	Linda Cowan	BaCT	Linda.Cowan@petermac.org	03-9656 3637
MDS4	Open	Linda Cowan	BaCT	Linda.Cowan@petermac.org	03-9656 3637
MM6	Follow up	Nola Kennedy	Alfred Hospital	N.Kennedy@alfred.org.au	03-9276 2217
MM8	Follow up	For information contact Peter Mollee		Peter.mollee@health.qld.gov.au	07-3240 2396
MM11	Closed	Nola Kennedy	Alfred Hospital	N.Kennedy@alfred.org.au	03-9276 2217
MM13	Set-Up	Ania Matera	BaCT	Ania.Matera@petermac.org	03-9656 3661
NHL11	Analysis	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
NHL13	Analysis	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
NHL14	Follow-up	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
NHL15/TROG 05.02	Open	Thao Le	BaCT	Thao.Le@petermac.org	03-9656 5268
NHL18	Follow up	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
NHL21	Open	Ruth Columbus	BaCT	Ruth.Columbus@petermac.org	03-9656 5827
NHL24	Open	Lavanya Gupta	BaCT	Lavanya.Gupta@petermac.org	03-9656 5807
NHL25	Open	Poppy Kypreos	BaCT	Poppy.Kypreos@petermac.org	03-9656 1268
NHLOW5/TROG 99.03	Open	Bev McClure	BaCT	Beverley.McClure@petermac.org	03-9656 1266
PTI	Open	Ruth Columbus	BaCT	Ruth.Columbus@petermac.org	03-9656 5827
SCO1 ASPID	Follow-up	For information contact Orla Morrissey		o.morrissey@alfred.org.au	03-9076 3009

## November 2011 Scientific Meeting



**8 - 11 Nov 2011**  
**Hilton Hotel**  
**Brisbane**

**All registrations and cancellations must be received by Friday, 28 October**

### The SAC welcomes you to the next ALLG Scientific Meeting

#### Your e-Invite

Your e-invite should have arrived in your Inbox by now. For all the information you need to register for and attend this event, see below.

#### Registration

**You MUST register through our online registration system if you are planning on attending the November Scientific Meeting in Brisbane.** You can only register by responding to the invitation email which arrives in your inbox. Each invitation is personalised, so you can't register from someone else's invitation. Please follow the four simple steps noted below to complete your registration.

1. To register, please **click the 'YES/NO' buttons** or the URLs located at the bottom of your invitation email. If you are not planning on attending, all you have to do is click the 'NO' button/link to avoid receiving scheduled reminders.
2. Please be sure to **choose the correct 'Participant Type'** under 'Registrant Information' on the first screen and complete your contact de-

tails. (If you have attended past events, your contact details will be automatically pre-filled and all you have to do is double check your information and update if necessary)

3. **Choose the sessions** that you will be attending. This is an important part of the process as this will provide us the final numbers in our planning process for hotel room set-up and catering.
4. **Book hotel accommodation** - Hotel accommodation is available for participants outside Brisbane. When booking your hotel accommodation, please be sure to indicate the accurate check-in and check-out dates. We strongly advise you to **double check your arrival and departure dates** noted in your 'Registration Confirmation' email to avoid any issues on the day of arrival. Any additional dates outside our roomblock, early check-in and late check-out times need to be noted under the 'Additional Requirements' textbox. Please keep in mind that this is subject to hotel availability and we will confirm closer to the date of arrival.

## Highlights - something for everyone

### Myeloma, myeloma and more myeloma

Well, we are up to MMI3 so it is appropriate that we again run the very popular educational on myeloma for the data managers/research nurses. It's on the Tuesday as usual. Learn about therapy for "young" and "old" patients, bone disease and supportive care and the rationale for our trials in this disease. Yes, it's on for young and old!

### Networking Breakfast - Thursday

Don't complain we don't think about your stomachs when planning scientific meetings. This is a new opportunity to meet your colleagues, discuss trials, have a laugh and eat a full plated breakfast with all the works - and all for free!!! Who wouldn't leap at the chance? This event on the Thursday is open to all meeting participants, and will provide 45 minutes of high quality intake and communication. Registration is necessary, via your Cvent invite.

### AML new studies breakfast - Thursday

For staff from all sites participating in the AMLM15 and AMLM16 studies. Absorb trial goodies while

eating your goodies. Andrew Wei will preside - what more can I say?

### Trial proposals

There are new ideas and concepts in NHL, myeloma, ET, CML and APLM. The alphabet is getting a real workout at this scientific

meeting. Come and hear about the new proposals from the various horses' mouths (excuse me - I mean worthy PIs).

### Early closing

The meeting is scheduled to finish at 3 pm on Friday, to make it easier for you to get away. Bon voyage!!



*You haven't quite got the hang of this breakfast networking have you?*

**Notice of General Meeting for ALLG Members Thursday 10 Nov 2011 2:30pm Hilton Hotel Brisbane**

<b>Agenda</b>	
<b>Tuesday, 8 November</b>	
10:00 – 17:00	Haematology Education for Data Managers/Research Nurses: Myeloma
<b>Wednesday, 9 November</b>	
09:30 – 17:00	Data Managers/Research Nurses Day
15:00 - 17:00	BMT DGC meeting
18:00 – 22:00	ALLG Scientific Advisory Committee Meeting (committee members only)
<b>Thursday, 10 November</b>	
07:30 – 08:30	Tissue Bank Committee Meeting (committee members only)
07:30 - 08:30	AML New Studies Breakfast Meeting (For AMLM15 and AMLM16 participating sites)
08:15 – 09:00	Networking Breakfast - NEW!!! ALL WELCOME!!!!
11:00 – 13:00	ALLG Board Meeting (members only)
09:00 – 17:00	<b>ALLG Meeting - Lymphoma Day</b>
	High Grade NHL and HL
	Myeloma
	Low Grade NHL and CLL
	CML and Myeloproliferative Neoplasms
14:30 - 15:00	<b>General Meeting: ALLG Members</b>
19.00 – 22:30	<b>ALLG Dinner</b> (Venue: Alchemy Restaurant and Bar. RSVP essential)
<b>Friday, 11 November</b>	
7.30 - 8.30	Laboratory Science Committee Meeting (committee members only)
08:30 – 15:00	<b>ALLG Meeting - Leukaemia Day</b>
	Tissue Bank Report
	Laboratory Science
	Acute Leukaemia and Myelodysplasia
	Supportive Care and Bone Marrow Transplant

## Alchemy - it's magic!

Dinner on Thursday night will be held at the Alchemy Restaurant and Bar, located in a stunning position on the Brisbane River. The venue has an atmosphere of relaxed elegance inspired by the exquisite cuisine and the spectacular views. Alchemy's definition suggests to 'conjure magic and enchantment, the transformation of base metals into gold' which is the very essence of this magnificent restaurant.

**Come join us and experience the Liquid Nitrogen Gastronomic Nibbles!**



**175 Eagle St, Brisbane**  
**7.00 Drinks, 7.30 Dinner**

As we can only accommodate a limited number of guests at this restaurant, please be sure to reserve your spot by registering through your eVite early. **If you need to cancel, please contact Dilu as soon as practically possible.**

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## Centre for Biostatistics and Clinical Trials (BaCT)

### Meta-analyses - Mathias Bressel explains

#### Summarising multiple studies

When doing a literature review, sometimes it is desirable to summarise the individual findings into a single statistic. Meta-analysis methodology goes beyond a traditional literature review by providing tools to synthesise and combine results of multiple studies in a way that increases the precision of treatment effect estimates and quantifies the variability of the results among the studies.

Meta-analysis may help to evaluate whether a planned study is necessary or if the information available in the literature already answers the question satisfactorily. In the event that a new study is needed, the meta-analysis can play an important role in determining the most-appropriate design of the new study.

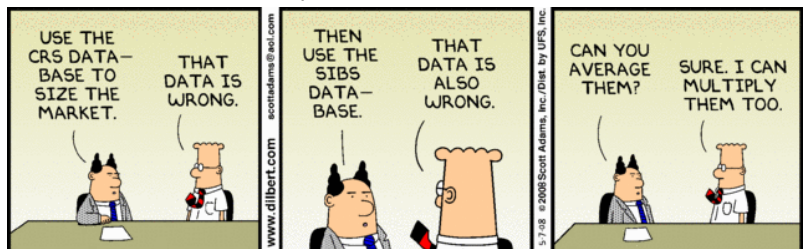
#### A relevant example

One example of meta-analysis is the study from Wang et al (*Wang J et al, Med Oncol 28: 822-828, 2011*), where the investigators evaluated whether overall survival was superior with standard chemotherapy compared to high-dose chemotherapy with autologous stem cell transplantation as the first-

line therapy for patients with aggressive non-Hodgkin lymphoma. They accessed 6457 studies and 14 were included in the meta-analysis. The results from the randomized clinical trials were conflicting (only 2 studies found a significant result favouring conventional chemotherapy while the others were inconclusive). By combining results from 14 studies into a single and more precise result using meta-analytic methods, investigators were able to conclude that HDCT decreased overall survival compared to conventional chemotherapy in aggressive non-Hodgkin lymphoma (HR=1.2, 95% CI [1.05, 1.37]).

#### Methodological rigor

Be mindful that meta-analysis is a research design that needs a similar degree of methodological rigor to that of a randomized clinical trial in order to produce reliable and meaningful results. Its exhaustive search of the evidence may require accessing a large number of articles. If you would like to find out more about meta-analysis or if you need help to do one, please come and talk to us at BaCT.



Gemma Tait, Trial Manager  
 AMLM15, AMLM16

### Welcome: Gemma Tait

Gemma Tait will be Trial Manager for the AMLM15 and AMLM16 trials. Gemma writes:

“I emigrated to Australia at the start of August from Scotland, where the peak of summer is more like the Melbourne winter so you can imagine how happy I am. I most recently worked in the Clinical Trials Unit of the Beatson West of Scotland Cancer Centre, Glasgow, which is the largest cancer treatment and research hospital in Scotland. I've worked in oncology clinical trials for 6 years now and while many of the regulations in the UK and Australia are similar, there are differences too so please bear with me while I learn all these new acronyms! “

### Trial Statisticians

Mathias Bressel	NHL15/TROG 0502
Marnie Collins	ALL3, CLL5, BM07, APLM4
Gaelle Dutu	CML6, CML8, CML10, CML7, AMLM16
Richard Fisher	NHL05/TROG 9903
Alan Herschtal	CML9, NHL21, CLL6
Emma Link	ALL5, AMLM12, AMLM13, MDS3, MDS4, NHL11, NHL_X08

Please contact the allocated Clinical Trial Manager in the first instance or otherwise statisticians. For any difficulties or trials not listed contact one of the following:

[Marianne Hundling](#)  
 BaCT Program Manager

[Dina Neiger](#)  
 Director



## Safety and Data Monitoring Committee



**SDMC Chair**  
**Peter Browett**

The SDMC said goodbye last time to Martin Stockler, who filled the **external medical position** on the Committee. In July they welcomed a new member in this position - **Chris Karapetis**, a medical oncologist from Flinders Medical Centre (see right). And another change has since occurred. **Ray Lowenthal**, who was previously the Chair of the committee and more recently an ordinary ALLG member has also stepped down. Ray was on the SDMC for 10 years. At the July meeting Peter thanked Ray for his input to the SDMC, his wisdom and significant leadership in the role as Chair. To read more about Ray's role on the SDMC see the [history section](#).

The SDMC is in the process of considering a number of trials still in development including the new BMT trial MAVRIC (now named BM11). This is the first

ALLG BMT trial in quite some time, and its development has been very much a team process. It is hoped that the SDMC will complete its review and approve it for activation very soon.

### Welcome Chris Karapetis

Ass Prof Chris Karapetis is a Staff Specialist and Director of Clinical Research in Medical Oncology at the Flinders Medical Centre in Adelaide. Following completion of a research fellowship at Guy's Hospital in London he returned to Adelaide to establish a clinical research unit at the FMC. As the principal investigator in on over 80 clinical trials he has established research interests in the areas of gastrointestinal malignancy, lung cancer, epidemiology, novel drug development, and clinical research methodology. He is a member of the Australasian Gastrointestinal Trials Group, a member of editorial boards, has acted as a reviewer for several medical journals and published over 50 scientific papers in peer-reviewed scientific journals.



*The SDMC operates independently and includes at least three external members. The SDMC reviews all new proposed protocols and amendments which must be approved prior to dissemination to the HRECs at sites. The committee also reviews regularly all currently accruing trials and closed trials with patients still on treatment.*

### Responsibilities of the SDMC

(Policy & Procedure Manual October 2010)

1. Reviewing all protocols proposed for ALLG participation, whether ALLG initiated or international.
2. Reviewing all proposed amendments to protocols prior to HREC submission
3. Reviewing urgent alerts involving safety issues and notifications that a stopping rule has been reached, if that stopping rule involves a safety issue.
4. Reviewing reports on accrual and safety, safety stopping rules, and interim toxicity data for trials
5. Reviewing reports on accrual and recruitment rates with specific attention to the likelihood of the study answering its proposed question.
6. Assessing the impact of independent scientific investigations, especially other trials, on the trial being monitored and recommending changes based on those external results
7. Ratifying any decisions made by other trial management committees

### Summary of decisions from the 25/7/2011 SDMC :

#### New studies approved to be activated

ALL6

#### Trial amendments approved:

AML15

#### Current trials reviewed and approved to continue

ALL5, ALL7, AML15, CLL5, MDS4, NHL15, NHL21, HD8, NHL24, NHL25, PT1

#### Closed trials reviewed

AML13, APML4, CML6, CML9, HDNHL4, NHL11, HD4, LY03, MDS3, MM11, NHL13, NHL14, NHL16, NHL18, NHL19,

For more information on any individual trial, contact the trial coordinator or PI

### SDMC membership

#### ALLG

Peter Browett (Chair)

Ray Lowenthal

Andrew Grigg

Tony Mills (SAC Liaison)

#### External

Patrick Kelly (Biostatistician)

Chris Karapetis (Medical)

John Stubbs (Consumer Rep)

#### BaCT Statistician

Alan Herschtal

### Upcoming SDMC meetings

Monday 10 Oct 2011 teleconference

Monday 13 Feb 2012 face to face

## Grant News

In August, the ALLG submitted an application to the Cancer and Bowel Research Trust for funding to support the SC03 study. This observational study will be the first to evaluate the incidence and severity of chemotherapy-induced nausea and vomiting in patients receiving R-CHOP and standardised anti-emetic prophylaxis.

An application to the Barr Family Foundation to support the ALL6 study is in preparation. The objective of ALL6 is to establish whether a pediatric acute lymphocytic leukaemia protocol can be given effectively to adolescents and young adults. ALL6 fits well with the key objective of the Barr Family foundation which is to enhance the lives of physically, mentally or health disadvantaged children and young people living in Victoria.

Unfortunately, ALLG applications to the Leukemia and Lymphoma Society (MDS4 correlative studies), Perpetual Trustees (salary support for Barwon Health trial unit) and the Leukaemia Foundation (EOI for MDS3 correlative studies) were unsuccessful.

Melissa Benedict

ALLG Grant and Training Coordinator



### Grant applications - status

Funding body	ALLG project	Status	Outcome due	Outcome
Perpetual	Barwon Health salary support	submitted		unsuccessful
Leukemia and Lymphoma Society	MDS4 correlative studies	submitted		unsuccessful
Ramaciotti Foundation	ALLG Tissue Bank support	EOI submitted		pending
Leukaemia Foundation	MDS3 correlative studies	EOI submitted		unsuccessful
Brain Foundation	NHL24 correlative studies	submitted		unsuccessful
ANZ Trustees	Cytogenetics Central Review	submitted		unsuccessful
Cancer & Bowel Research Trust	SC03	submitted	Nov 2011	
NHMRC/PdCCR	HD8/NHL21 lab studies	submitted	Oct 2011	
Barr Family Foundation	ALL6	submitted	Dec 2011	

### Granting bodies - current funding

The ALLG acknowledges funding received during 2011 from the following sources:

NHMRC enabling grant (round 3)	Tissue Bank	extended to March 2012
Cancer Australia	infrastructure	ceases end 2011
PdCCR Scheme	HD8 trial	ceases end 2012
HOTTAH grant (COSA/Roche)	ALLG Management Database	ceased Aug 2011
AYA Canteen	ALL6 trial	annual

## Training news

### Specialist Certificate in Clinical Research



Melissa Benedict

ALLG Grant and Training  
 Coordinator

**To express interest in the 2012 scholarship contact [Melissa Benedict](#) for an EOJ form. Deadline for receipt of the full application is 9 Dec 2011. Decision will be announced in January**

In February 2011, the ALLG, with the support of Merck, Sharp and Dohme, offered four scholarships to ALLG members to attend the **Specialist Certificate in Clinical Research (Oncology)** course at the University of Melbourne. This intensive course aims to provide participants with an understanding of the breadth of research in oncology and career opportunities as well as ethical and legal considerations relevant to clinical oncology research. Students also gain an appreciation of **how to develop research proposals/study protocols** and skills in the critical appraisal of presentations and publications in oncology research. The course requires participants to attend two four-day sessions on site at the University of Melbourne and complete a number of assessments.

This year, Dr Amanda Johnston (Westmead Hospi-

tal), Dr Ashish Bajel (Royal Melbourne Hospital), Dr Ketan Bavishi (Cairns Base Hospital) and Chris Twyford (Canberra Hospital) received scholarships to attend the course. All four participants found the course highly relevant and recommended it to peers pursuing a career in clinical research.

**Amanda Johnston** commented: "Participating in the course has provided inspiration as well as practical background knowledge and skills that will enhance my participation as an investigator in ALLG trials and hopefully, after further experience, enable me to be involved in trial development as well as training. I would recommend the course to final year advanced trainees in Haematology and junior staff specialists with an interest in clinical research and specifically clinical trials. The amount of knowledge gained in such a short period of time is invaluable."

### Applications for 2012

The 2012 course will be held at the University of Melbourne in two four-day sessions, probably late March and late June. **Part 1 focuses on key principles and fundamental knowledge** in clinical research in oncology. **Part 2 expands on these principles and outlines research in various areas** including translational research, health economics, quality of life and statistics. This is an intensive course and a significant amount of previous knowledge and experience is assumed, particularly in the area of clinical oncology. Course participants are expected to attend the classroom sessions and complete several assignments and an exam.

The funding for scholarships is from an education grant from Merck Sharp & Dohme. **Four ALLG scholarships will be available in 2012** – three for clinician members and one for an associate member of the group. Applicants who were unsuccessful in previous years may apply again. Course fees will be paid by the ALLG and travel assistance can be provided for non-Melbourne participants. Further details about the course, including confirmed dates, will be available in October/November.

### GCP training in 2011

This year, the ALLG provided several opportunities for Members and Associate Members to undertake GCP training. Nine research nurses/data managers attended GCP training with Nucleus Network or affiliate organisations, Beltas and Clinical Network Services, in 2011. This two-day classroom-based course is particularly suited to individuals who are new to clinical trials research.

**Jacquie Ruhl, from Royal Darwin Hospital,** commented: "As I have limited experience in this field, the GCP training has helped me to gain essential insight into how to manage trials within the GCP

guidelines. As well as governing my everyday practice I will use the experience to further develop SOPs for the department and hopefully find a way to streamline HREC applications in the NT." All participants recommended the course to their peers.

**Monika Swierk from Royal Perth Hospital** remarked: "I had received excellent feedback from others about this course prior to attending, and after attending myself, I would highly recommend this course to others who are new and/or interested in implementing a high standard of GCP at their site."

## Timely and engaging GCP at Westmead/Nepean

We have all heard it: “if it isn’t documented it didn’t happen”. But as soon as the words GCP are uttered, our investigators’ eyes glazed over, watches were checked and prayers were said for an “urgent” patient emergency.

So the challenge was, how to do GCP in a **timely and engaging manner**? The answer came from Eleanor Allan, from Caledonian Consulting and had glowing recommendations.

I picked a “low activity” Friday several months in advance and then **reminded them every couple of weeks**. I finally stated the only excuse would be death – no sick certificates allowed!!

Eleanor and I planned for the session to be brief (half a day), engaging and primarily focused on GCP and we discussed the background on department, experience mix, types of trials, and our weaknesses.

The day dawned – I wondered how many excuses of “**the kids hid my car keys**” or “**the dog has died**” I would receive, or would the investigators ever forgive me. But all scheduled attendees turned up (caffeine and matchsticks in hand).

First off was an outline of the guidelines & regulations governing GCP and then we were quickly into a case study in groups based on the guidelines, highlighting the **role of the sponsor, investigator and HREC** in the conduct of a trial. One of the groups got all the questions correct – not surprisingly this included our illustrious leader Mark Hertzberg, although I think he had an unfair advantage with Dr Amanda Johnston in his group, who has just completed her Masters in Clinical Research! The key message from this session was as the Principal Investigator for a study you should only delegate to appropriately qualified and competent people; you are

personally responsible for the entire oversight of the study, and ultimately “**the buck stops with you**”.

Another group session looked at the **frequent FDA audit findings** and how to prevent this from occurring at our site. One of the key points was how we could improve our documentation. The investigators gained insight as to why ECOG PS must be written, not just “patient fine”, and adverse events needed to be documented as ongoing or ended at each study visit.

We reviewed the **informed consent process** and how it could be improved. One idea that I use is to suggest to the patient they take their PICF to their GP for an independent perspective. However, one question did remain: “How do you know you have actually got **informed** consent?”.

The case studies and group work were very engaging with lots of discussion and great examples from Eleanor. It was refreshing to have GCP presented in a realistic way whilst conveying formal responsibilities. Eleanor understood time limitations for investigators and that sometimes there is a need to **negotiate an appropriate** solution with sponsors.

Afterwards, the investigators were actually disappointed it was over. Some comments: “Thank you – you made a notoriously dull subject engaging”; “Interactive nature definitely improves the interest and relevance”; “Excellent, could have gone longer, and “Group discussion of individual problems with group correlation subsequently was very useful”.

**A follow up clinical trial meeting** will review and discuss our current procedures/processes to improve our compliance with GCP.

Angela Bayley, Westmead Hospital

**The PI should only delegate to appropriately qualified and competent people; you are personally responsible for the entire oversight of the study**



## ALLG Operations Office

The main news exciting us in the Ops Office is Delaine's elevation. No, she hasn't grown taller, and she isn't wearing platform heels. She's been promoted to Chief Executive Officer!

Delaine was appointed Operations Manager in May 2008. Since then she has built the Operations Office up to a well functioning team of 6 staff, who manage all the aspects of the administration of the ALLG and support the Board, the SAC, the SDMC and other committees. In her three years in the role, Delaine has become well know to all the members. She is recognised for her exceptional trial and administrative expertise - and also for her trivia quizzes!!!

As CEO, Delaine will lead further the strategic development of the group, the enhancement of its infrastructure and the greater implementation of its clinical trial and translational research program portfolios.



The Ops staff are delighted about Delaine's appointment.

Pictured (left to right) are: Dilu Uduwela, Delaine Smith, Janey Stone, Melissa Benedict.



**For any membership or subscription queries or for site approval information please contact [Dilu Uduwela](#).**

## Membership matters

### Welcome to our new members

Catherine McCarthy	Royal Brisbane & Women's	Marcel Knesl	Nambour General
George Grigoriadis	Alfred Hospital	Toby Trahair	Sydney Children's Hospital
Sarah Moore	SA Pathology	Wendy Erber	Uni of Western Australia
Agnes Yong	SA Pathology	Rachel Conyers	Peter MacCallum
Ashanka Beligaswatte	Royal Adelaide	Annie Chow	Royal Adelaide Hospital
Steven Lane	Royal Brisbane & Women's	Nicole Wong Doo	Peter MacCallum

### Associate membership

This year a new category of membership has been added to the ALLG. Data managers, research nurses, scientists and others can now become an associate member. The new category was set up as a way of strengthening the relationship of site trial staff with the group. Associate members are people who have an affiliation with the ALLG as a result of their employment position or affiliation with the group. They have no voting rights, cannot be a PI of a trial and do not qualify for membership of the Board, SAC, SDMC or other constitutionally established committees.

Associate members do not pay a membership fee and can join by simply completing the application form available from Dilu. The application must be supported by a clinician ALLG member at your site.

## The way we were....the SDMC

This is our regular history corner. If you have an anecdote, some information or topic you would like to include - or better still contribute - just contact Janey Stone. And reading this carefully will be worth your while.... trivia quizzes at future scientific meetings will feature information reported here. So, go to it!!

**D**id you know....??

The ALLG Safety and Data Monitoring Committee commenced activities on 1 November 2002 with a teleconference. The first Chair was Phil Rowlings and other committee members included Graham Young, Judy Simpson, Martin Stockler, John Stubbs and Jane Matthews.

**The first things the SDMC had to decide** was its own role and activities and even its own name. It quickly came to the agreement that the role of the committee was to ensure required standards of safety and data monitoring are met for all trials in which ALLG is involved. This is a short sentence but has proved to be a big task and a central one for the committee ever since. Topics that needed to be decided included whether the committee's powers were advisory or decision making, its role in review of proposed new protocols and in monitoring ALLG studies. How international studies fitted in also exercised the members minds at this first meeting, which also established in draft form many of the procedures that are still followed today.

### 2003 - a good year

The SDMC met twice in 2003, with Graham Young as "acting" chair. This temporary arrangement was to last for two years!! A critical decision was to review all new protocols whether ALLG-initiated or international.

An important standard was set: the SDMC in its review would **pay particular attention to stopping rules and safety and data monitoring** procedures. If these were not deemed adequate, then the ALLG would not participate. Having decided to review all current trials twice a year, emphasis was again placed on accrual, safety and stopping rules. Each PI would be asked to provide to the SDMC a written assurance that he or she knows of no information from external sources which would compromise the continuation of the study, and any other relevant information relating to the continuation of the study. In November John Moore joined the committee as Executive liaison.

### Graham Young left his mark

Graham Young was chair of the committee in its most formative years, and certainly left his mark. He was responsible for **defining its standards of integrity, impartiality and ethical responsibility**. Given that almost everything was new, Graham spent an lot of time and energy simply corresponding, discussing and answering queries and trying to balance the varying points of view.

### A Ray of sunshine...

Ray Lowenthal joined the SDMC in November 2003, and had a distinguished career with the committee. For the first two years he was an "ordinary" member, although it must be said that nothing is ordinary about Ray! He was a founding member of the Australian Leukaemia Study Group (a predecessor group of the ALLG) and therefore was already a very longstanding

and active member.

He brought his very considerable expertise in the whole of haematology, but very particularly in AML trials to the deliberations of the SDMC. Ray was a PI on the very first group AML trial, and then was the driving force behind the introduction of Idarubicin to replace Daunorubicin in the group's AML trials. Ray became Chair of the SDMC in 2005 and remained to September 2009.

### P(arty) and P(leasure)???

The topic of policies and procedures is not necessarily the most exciting one, but the establishment of a P&P Manual was a landmark event for the SDMC in early 2004. One critical discussion involved the SDMC's **role as an independent body** and its interaction or relationship with trial management committees. The committee agreed that the SDMC has to be seen to be at arm's-length from a study team. But it would be unfortunate if this requirement discouraged investigators from serving on the SDMC.

*"The smallness of the research community means that we can't be totally pure as most SDMC members are participating in trials - we need a compromise position."*

### A consuming involvement - John Stubbs

No history of the SDMC would be complete without mentioning our consumer representative John Stubbs. John has **served on the committee since its inception** and is its longest serving member. As well as being the consumer rep on the ALLG SDMC, John Stubbs is Executive Officer of Cancer Voices Australia and a regular speaker at medical conferences and seminars on cancer advocacy, clinical trials and health related issues. This was the first formal involvement of a consumer representative with the ALLG.

**Do you know any early stories or want to request something? Send your contributions to Janey Stone**



**An SDMC Distinguished Gallery.** From top to bottom, John Stubbs, Graham Young, Ray Lowenthal

## Around the traps - site news

### Cancer Trials Australia



## Cancer Trials Australia

Cancer Trials Australia (CTA) is a not for profit, membership based organisation. Originally called CDCT, it was established in the early 1990s to relieve investigators and nurses of the administrative aspects of running clinical trials and to provide a network of information sharing and patient referrals.

Since then the group has grown to include 14 clinical and 2 non-clinical sites: Alfred Health, Austin Health, Ballarat Health, Bendigo Health, Border Medical Oncology, Cabrini Health, Ludwig Institute for Cancer Research, Melbourne Health, Peninsula Oncology Centre, Peter MacCallum Cancer Centre, St Vincent's Health (Melbourne), Southern Health, Walter & Eliza Hall Institute, Royal Women's Hospital, Tweed Hospital and Western Health. Many of these are ALLG trial sites.

Our staff keep up to date with any change in regulatory processes, for example the national approach to streamlined ethical review, and we are heavily involved in working groups and advisory groups such as the Clinical Trials Action Group.

CTA's services include ethics submissions, research governance, clinical advisory groups and financial management. Of the advisory groups haematology is one of the biggest and is currently chaired by Dr William Renwick. The group meets quarterly to evaluate feasibility studies, review progress of clinical trials and facilitate patient referrals.

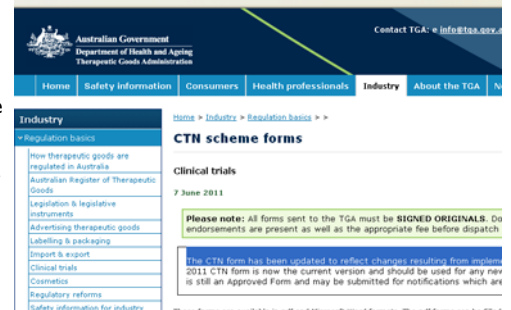
Our customers include collaborative research groups, biotechnology firms and large pharmaceutical companies.

To visit the website [control/click here](#) and for more information contact [Sarah Bascomb](#).

*Sarah Bascomb*

### TGA updates CTN

The TGA has updated the CTN form and all new submissions must use the new version dated May 2011. The update is to reflect changes resulting from implementation of the new Biologicals Framework. The new form is available from the [TGA website](#) and the ALLG website has been updated with the correct link to the new version of the form. Please use the new form for all new trials.



### ALLG site approvals - new approach

A revised form to assess sites wishing to participate in ALLG trials is now available. On the principle that bigger is better, the new form covers three pages and collects a wider range of pertinent information. The ALLG needs to ensure that sites are suitably set up and staffed to conduct trials in accordance with the various laws, regulations, guidelines and principles according to which we all operate.

The form includes ethics committee, clinical services, patient groups, clinical research staff resources, diagnostic facilities and trial involvement. Having been put together by a committee, the new version is completely comprehensive.

All new sites applying to participate in ALLG trials will need to complete this form. They can then join the select group of approved sites listed on the right. There are no plans for retrospective completion, so you can all breathe easy. For any queries contact Dilu in the ALLG Ops office.



## Approved ALLG sites - all 85 of them!

Names - they can be so confusing sometimes. And just as you get used to them, they get changed! For instance, did you know that the East Coast Cancer Centre is now called Premion? So we thought you'd like a complete list of all the ALLG trial sites, including satellite sites.

### Australia

ACC Adelaide Cancer Centre  
 ALF Alfred Hospital  
 AUS Austin Hospital  
 BAL Ballarat Oncology & Haematology Services  
 GEE Barwon Health (Geelong Hospital / Andrew Love Cancer Centre)  
 BEN Bendigo Hospital  
 BMO/ALB Border Medical Oncology (Albury Base/ Murray Valley Private Hospital)  
     BMO Satellites  
         Albury Wodonga Health  
         Ramsay Health Care  
 BXH Box Hill Hospital  
 CAB Cabrini Hospital  
 CNS Cairns Base Hospital  
 CAN Canberra Hospital  
 WCH Children, Youth and Women's Health Service  
 CHW Children's Hospital at Westmead  
 COF Coffs Harbour Health Campus  
 CON Concord Hospital  
 FMC Flinders Medical Centre  
 FRA Frankston Hospital  
     FRA satellite:  
         Peninsula Oncology Centre  
 FRE Fremantle Hospital  
 GCH Gold Coast Hospital  
 GOS Gosford Hospital  
 RHG Greenslopes Private Hospital  
 HOC Haematology Oncology Clinics of Aust  
 JFM John Flynn  
 JHC John Hunter Childrens  
 LAU Launceston Hospital  
 LIS Lismore Hospital  
 LIV Liverpool Hospital  
 MBH Mater Brisbane Hospital

MCH Mater Children's Hospital  
 MMN Mater Newcastle  
 MPC Mater Private Medical Centre  
 MON Monash Hospital  
 MOU Mount Hospital  
 NAM Nambour General Hospital  
 NEP Nepean Hospital  
 NSH North Shore Hospital  
 NOH Northern Health/The Northern Hospital  
 PMC Peter MacCallum Cancer Centre  
 PMB Port Macquarie Base Hospital  
 PRT Premion (Private radiotherapy centre for NHL15)  
 POW Prince of Wales  
 PAH Princess Alexandra Hospital  
 QEH Queen Elizabeth Hospital  
 QRM Queensland Radium Institute  
 ADE Royal Adelaide Hospital  
 RBH Royal Brisbane Hospital  
 CHB Royal Children's Hospital, Brisbane  
 RCH Royal Children's Hospital, Melbourne  
 DAR Royal Darwin Hospital  
 HOB Royal Hobart Hospital  
 RMH Royal Melbourne Hospital  
 RNS Royal North Shore Hospital  
 RPH Royal Perth Hospital  
 RPA Royal Prince Alfred Hospital  
 SCG Sir Charles Gairdner  
 STG St George Hospital  
 STV St Vincent's Melbourne  
 SVH St Vincent's Sydney  
     SVH satellite:  
 GBH Griffith Base Hospital  
 SHO Sydney Haematology and Oncology Clinics  
 TAM Tamworth Base Hospital  
 TOO Toowoomba Hospital

TOW Toowoomba Hospital  
 TWE Tweed Hospital  
 WMC Wesley Hospital  
 WGH Western Hospital  
 WES Westmead Hospital  
 WIM Wimmera Base Hospital  
 WOL Wollongong Hospital

### New Zealand

AUC Auckland Hospital  
 CHR Christchurch Hospital  
 DUN Dunedin Hospital  
 MID Middlemore Hospital  
 PNH Palmerston North  
 TAH Tauranga Hospital  
 WAI Waikato Hospital  
     WAI satellite:  
 ROH Rotorua Hospital  
 WEL Wellington Hospital

### Canada

PMH Princess Margaret (Toronto)  
 PMP Princess Margaret Hospital for Children

### South Africa

JOH Johannesburg  
 PRE Pretoria



Border Medical Oncology

## Lime for Lymphoma!



The sails of the Sydney Opera House were lit a stunning lime green on September 15 by Lymphoma Australia to mark World Lymphoma Awareness Day and to show Australia and the world that Lymphoma matters.

Lymphoma Australia's guests enjoyed a fun filled, gala night at the Cruise Restaurant surrounded by lime green lights and feathers to support awareness for this cancer.

The feather is the official logo of Lymphoma Australia and is "a symbolic representation of a guardian angel being there for anyone facing a Lymphoma journey."

### Green sales in the sunset

Mark Hertzberg and Judith Trotman attended the gala event and clearly had a great time (middle photo with Lymphoma Australia Ambassador, Johnny Mannah).

The lower photo shows the three of them together with some young lymphoma patients.

World Lymphoma Awareness Day (WLAD) is held on September 15 every year and is a day dedicated to raising awareness of lymphoma. WLAD is a global initiative hosted by the Lymphoma Coalition, a non-profit network organisation of



50 lymphoma patient groups from 37 countries around the world including Lymphoma Australia.

### Galloping Greens

This was not the first time lime has been used to highlight lymphoma. In August the Randwick Rugby Club renamed themselves the "Galloping Greens" and wore lime green socks at a game at Coogie oval in support of a former player diagnosed with NHL. Five "lime girls", decked out in lime green feather boas and makeup, wound their way through the crowd, buckets in hand.



For more information on the activities of Lymphoma Australia, visit their website (control/click [here](#))

## Leukaemia Foundation

A short note to bring everyone up to date with some staff and role changes at the Leukaemia Foundation. Anna Williamson is looking after Research and Advocacy activities and all patient support services and education programs are being managed by Anthony Steele. We have welcomed Jacinta Ridge, a new staff member, who is providing to executive support to both Anthony and Anna. We are based in the national office of the Foundation in Brisbane.

The Leukaemia Foundation is dedicated to the care and cure of patients and families living with leukaemias, lymphomas, myeloma and related blood disorders. The Foundation provides a range of free support services including blood cancer information, education seminars and programs, practical assistance, accommodation, transport and emotional support. Our organisation funds research through grants in aid, fellowships and scholarships as well as supporting research facilities including the Leukaemia and Lymphoma Tissue Bank and the Leukaemia Foundation Research Unit at QIMR.

We also plan a patient booklet promoting the benefits of participating in clinical trials and we would welcome any volunteers from ALLG to help us – please contact Anthony. Meanwhile, we are happy to help you or your patients in any way we can.

Anna Williamson



The team at the Leukaemia Foundation, left to right:

[Anna Williamson](#) (07-3866 4060)

[Jacinta Ridge](#) (07 3866 4038)

[Anthony Steele](#) (07 3866 4061)

## Patient educational days, from Adelaide to Darwin

**Emma Link from BaCT** was part of a very successful Patient Education Day run by the Leukaemia Foundation in Adelaide in July. In the thank you letter the comment was made that the constituents of the LF need to understand both the importance of clinical trials and the various methods of allocation to clinical trials. *"It was good to be able to have them exposed to the science behind allocation"*.

It is a specialised skill to be able to explain statistical concepts to a lay audience and the slide here shows that Emma captured the main point purrfectly...

### Meanwhile, in the Top End

We at the Leukaemia Foundation here in **Darwin** were more than pleased to serve up our Inaugural Patient Education Day for the Northern Territory.

We held this event at Skycity Casino in Darwin on Saturday July 9th, 2011. We structured the day around a panel of 6 speakers. **Dr Wei** represented our keynote speaker as he kicked off the day. He was followed by Dr. Giri from Adelaide who spoke on lymphomas, then Kim Hobbs from Westmead Hospital in Sydney spoke on Sexual and Emotional Health. We concluded the day with various local

### Randomisation – random allocation to one of two groups

- Coin toss (outcome: head or tail)
- Unpredictable ahead of time
- Can't be influenced
- Expect that, in the long run, everybody has the same chance of getting a head or tail, or being allocated to group A or group B



*Peter Mac*

complementary health specialists i.e. chiropractor, yoga specialist who delivered topics on self-care and wellness issues. And finally a local psychologist delivered the topic called **"Chemo Brain"** for a better understanding of how chemotherapy can affect cognitive function in patients. The event attracted 50 attendees including LF staff and speakers, of which 36 of the attendees comprised haematological patients and their family members and guests.

## Publications 2011

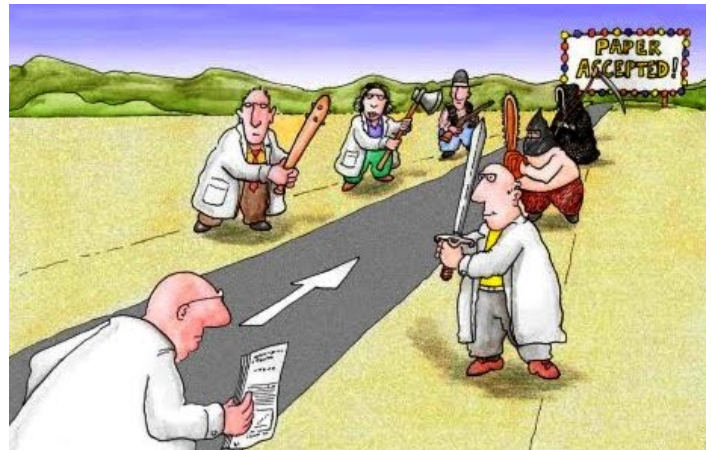
**IS YOUR NAME MISSING?** If your publication or abstract isn't listed here, it's not because we don't like you, but because we don't know about you. Please, *PLEASE, PLEASE* let us know about your publications, so we can give you and the ALLG due credit. (Note: abstracts for ASH will be listed in the December issue)

- A Wirth, A Grigg, M Wolf, D Goldstein, C Johnson, S Davis, G Dutu, P Kypreos, C Smith, A Kneebone, M Hertzberg, D Joseph, J Catalano, D Roos, J Stone, J Reynolds. Risk and Response Adapted Therapy for Early Stage Hodgkin Lymphoma: A Prospective Multi-Centre Study of the Australasian Leukaemia and Lymphoma Group/Trans-Tasman Radiation Oncology Group. *Leukaemia and Lymphoma*. 52: 786 – 795, 2011 HD3
- G Salles, JF Seymour, F Offner, A López-Guillermo, D Belada, LXerri, P Feugier, R Bouabdallah, JV Catalano, P Brice, D Caballero, C Haioun, LM Pedersen, A Delmer, D Simpson, S Leppa, P Soubeyran, A Hagenbeek, O Casasnovas, T Intratumorinchai, C Fermé, M Gomes da Silva, C Sebban, A Lister, JA Estell, G Milone, A Sonet, M Mendila, B Coiffier, H Tilly. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomised controlled trial. *Lancet* 377: 42-51, 2011 NHL16
- CO Morrissey, S Chen, TC Sorrell, KF Bradstock, J Szer, CL Halliday, NM Gilroy, AP Schwazer, MA Slavin. Design issues in a randomized controlled trial of a pre-emptive versus empiric antifungal strategy for invasive aspergillosis in patients with high-risk hematologic malignancies. *Leukaemia & Lymphoma* 52: 179-193, 2011 SC01
- Salles G, Seymour JF, Offner F, Lopez-Guillermo A, Mege L, Tilly H: Rituximab maintenance therapy for follicular lymphoma – Authors' reply. *Lancet* 377:1151-2, 2011 NHL16
- Trotman, J., Fournier, M., Lamy, T., Seymour, J. F., Sonet, A., Janikova, A., Shpilberg, O., Gyan, E., Tilly, H., Estell, J., Forsyth, C., Decaudin, D., Fabiani, B., Gabarre, J., Salles, B., Van Den Neste, E., Canioni, D., Garin, E., Fulham, M., Vander Borgh, T. and Salles, G. Positron Emission Tomography-Computed Tomography (PET-CT) after induction therapy is highly predictive of patient outcome in follicular lymphoma: analysis of PET-CT in a subset of PRIMA trial participants. *J Clin Oncol* 29: 3194-3200, 2011 NHL16
- A van der Jagt, J Muirhead, J.F.Seymour, K.F. Bradstock, E Paul and A.Wei. Risk factors for early death after high-dose cytosine arabinoside (HiDAC) based chemotherapy for adult AML. *Leukaemia*, August 2011 AMLM7
- JX Gray, L McMillen, P Mollee, S Paul, S Lane, R Bird, Devinder Gill, R Saal, P Marlton. WTI expression as a marker of minimal residual disease predicts outcome in acute myeloid leukemia when measured post-consolidation. *Leukaemia Research* (accepted for publication) LS13
- Pfreundschuh M, Kuhnt E, Trümper L, Osterborg A, Trneny M, Shepherd L, Gill DS, Walewski J, Pettengell R, Jaeger U, Zinzani PL, Shpilberg O, Kvaloy S, de Nully Brown P, Stahel R, Milpied N, López-Guillermo A, Poeschel V, Grass S, Loeffler M, Murawski N; for the MabThera International Trial (MInT) Group. CHOP-like chemotherapy with or without rituximab in young patients with good-prognosis diffuse large-B-cell lymphoma: 6-year results of an open-label randomised study of the MabThera International Trial (MInT) Group. *Lancet Oncol*. 2011 Sep 20. [Epub ahead of print] NHL10

## Presentations 2011

- Koh E, Wirth A, Seymour JF, Barton MB, Gabriel GS: Variability in long-term follow-up of Hodgkin lymphoma (HL) survivors: An Australian and New Zealand (ANZ) Patterns of Care Study (ALLG HD9). *Asia-Pac J Clin Oncol* 6(Suppl. 3):139, 2010 (Abstr. 158) HD8
- JM Stone. Lost in space? Long term follow ups, survivorship and archiving. *AHRDMA ASM*, Melbourne, March 2011 (oral presentation) NHL7
- M.Bouteloup, J. F. Seymour, P. Feugier, F. Offner, A. Lopez-Guillermo, R. Bouabdallah, L. M. Pedersen, P. Brice, D. Belada, G.Salles. Pattern of infections observed during the maintenance phase in the PRIMA study. 11th International Conference on Malignant Lymphoma, Lugano, 2011 NHL16
- F. Morschhauser, J. Seymour, P. Feugier, F. Offner, A. Lopez-guillermo, R. Bouabdallah, L. Pedersen, P. Brice, D. Belada, L. Xerri, G. Salles. Impact of induction chemotherapy regimen on response, safety and outcome in the PRIMA study. 11th International Conference on Malignant Lymphoma, Lugano, 2011 NHL16
- H Ghesquieres, J Seymour, F Offner, P Feugier, P Brice, C Haioun, O Casasnovas, J Catalano, F Jardin, L Xerri, G Salles. FCGR3A polymorphism does not significantly affect response and outcome of follicular lymphoma patients treated in the PRIMA study with rituximab and chemotherapy followed by rituximab maintenance or observation. 11th International Conference on Malignant Lymphoma, Lugano, 2011 NHL16
- Kenealy M, Wong N, Maksimovic A, Filshie R, Seymour JF: Do genome scale methylation changes in patients with MDS treated with azacitidine and thalidomide correlate with response to treatment? *Leuk Res* 35(Suppl. 1):S69, 2011 (Abstr 176) MDS3
- Kenealy M, Filshie R, Link E, Cowan L & Seymour JF on behalf of the ALLG: Results of a phase-II study of thalidomide (Thal) and azacitidine (Aza) in patients with clinically advanced myelodysplastic syndrome (MDS). *Leuk Res* 35(Suppl. 1):S22, 2011 (Abstr 60) MDS3
- P Mollee, C Tiley, I Cunningham, J Moore, M Prince, P Cannell, S Gibbons, J Tate, S Paul, D Gill. A Phase II Study of Risk-Adapted Intravenous Melphalan in Patients with AL Amyloidosis. *Haematologica* 2011;96(s1):S155. MM8
- Gandhi M, Hertzberg M, Han E, Keane C, Lopez A, Radford K, Seymour JF, Gill D, Vari F: The kinetics of systemic cellular immunosuppression in patients with poor-risk diffuse large B-cell lymphoma during treatment with "CHOP-R": A prospective study from the ALLG. *Haematologica* 96 (Suppl. 2):143, 2011 (Abstr 0345) NHL21
- Owen RG, Johnson SA, Lejeune J, Tournilhac O, Morel P, Ewings M, Chevret S and Leblond V. International Phase III study of chlorambucil versus fludarabine as initial therapy for Waldenstrom macroglobulinemia and related disorders: results in 414 patients. Sixth International Workshop on Waldenstrom's macroglobulinemia, Venice 6-10 October 2010. LY03

- Owen RG, Johnson SA, Lejeune J, Tournilhac O, Morel P, Ewings M, Chevret S and Leblond V. International Phase III study of chlorambucil versus fludarabine as initial therapy for Waldenstrom macroglobulinemia and related disorders: results in 414 patients. Sixth International Workshop on Waldenstrom's macroglobulinemia, Venice 6-10 October 2010. LY03
- Yeung D, Osborn M, White D, Branford S, Kornhauser M, Slader C, Hiwase D, Hertzberg M, Schwarzer A, Filshie D, Arthur C, Kwan Y, Forsyth C, Ross D, Mills A, Grigg P, Hughes T. CML patients failing to achieve MMR by 12 months may benefit from dose escalation or switching to nilotinib: A 24 month update of results from the Tidel-II trial. European Haematology Association Abstract 2011 CML9
- C Gisselbrecht, B Glass, N Mounier, D Gill, DC Linch, M Trneny, A Bosly, O Shpilberg, H Hagberg, N Ketterer, D Ma, P Gaulard, C Moskowitz and N Schmitz. Maintenance with rituximab after autologous stem cell transplantation in relapsed patients with CD20 diffuse large B-cell lymphoma (DLBCL): CORAL final analysis. ASCO Meeting abstracts J Clin Oncol Jun 9, 2011;8004 C (oral presentation) NHL13
- C Gisselbrecht, B Glass, N Mounier, D Gill, DC Linch, M Trneny, A Bosly, O Shpilberg, H Hagberg, N Ketterer, D Ma, P Gaulard, C Moskowitz and N Schmitz. Salvage regimen with autologous stem cell transplantation with or without rituximab maintenance for relapsed diffuse large B-cell lymphoma (DLBCL): CORAL final report. Ann Oncology, Volume 22 suppl 4 June 2011 #75 (oral presentation) NHL13
- M. Pfreundschuh, E Kuhnt, L Truemper, A Osterborg, M Trneny, L Shepherd, D. Gill, J. Walewski, R. Pettengell, U. Jaeger, PL Zinzani, O Shpilberg, S Grass, N Murawski, V. Poeschel, M. Loeffler. 6-year follow-up of the MINT study suggests a role for radiotherapy to bulky disease. 11th International Conference on Malignant Lymphoma, Lugano, 2011 NHL19
- Leblond V, Lejeune J, Tournilhac O, Morel P, Dihuydy M, Dartigeas C, Seymour JF, Malphette M, Royer B, Chevret S, Johnson S, Owen R: International phase III study of chlorambucil versus fludarabine as initial therapy for Waldenström macroglobulinemia and related disorders: Results of 414 patients on behalf of FCGLL/WM, GOELAMS, GELA and NCRI. Ann Oncol 22(Suppl. 4):iv128, 2011 (Abstr 134) LY03



## News and Views

### Human Research Ethics Portal on line

The Human Research Ethics Portal was launched in July. The Portal includes information on the National Approach (Homer Initiative), the National Certification Scheme, along with a list of certified institutions and the meeting dates for their relevant Human Research Ethics Committees. As well there is a toolbox of links to national guidelines, guidance material for multi-centre research, standardised participant information and consent form templates, HREC letter templates and information on indemnity and insurance. This portal is likely to prove increasingly important as it is developed over time. To visit the website control/click [here](#).

### ANZTPA - unpronounceable but important

Nearly 8 years after deciding to do so, the Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic goods (ie medicines, medical devices, etc). Over time, the joint arrangements will be administered by a single regulatory agency, the Australia New Zealand Therapeutic Products Agency, which will absorb the current regulators - Australia's Therapeutic Goods Administration and New Zealand's Medsafe. The process commenced in July and is expected to take 5 years to implement. In the long run, this will (hopefully!!) facilitate the trials we run in both countries. For more information control/click [here](#).

## Introducing: AHRDMA

The **Australasian Health and Research Data Managers Association (AHRDMA)** was established in 1990 as a non-profit organisation. AHRDMA is administered by an 8 person volunteer Executive Committee elected annually by the financial members of AHRDMA at the AGM which is held during the Annual Scientific Meeting. The main aim of AHRDMA is to facilitate contact and communication between data managers working within the field of medical research. This includes not just trial coordinators, but data managers working at registries, involved in audits and in many other areas. Other group aims are:

- Promote and maintain the quality of data management of medical research throughout Australasia
- Facilitate the continuing education and training of data managers
- Promote a forum for discussion and exchange of experiences, information and ideas between data managers in Australasia
- Improve the professional standards and standing of data managers in Australasia
- Establish contact and mutually beneficial interaction and relationships with other national and international professional and data management groups

### Change is just around the corner

Writing in the recent group newsletter, Paul Newman comments that the time of the institute or hospital based researcher has returned. Paul points out that times are changing in clinical and hospital research in Australia. With pharma trials now being managed from outside Australia, "this shift of focus means that the group of professional people who have always been the foundation of health research and data in Australia are returning to the fore."

### Annual Scientific Meetings

AHRDMA holds a Scientific Meeting each year. The 2011 ASM, held in Melbourne, was a well-attended meeting which showcased presentations across a diverse range of topics. Participant feedback indicated that the meeting contained relevant content and engaging speakers, in addition to serving as an excellent opportunity for networking.

The **keynote speaker** Prof Richard Sinnott gave a riveting presentation on how to empower the progress of research and development through the use of secure robust and intelligible technology platforms. Datasets for research are increasing exponentially and the expectation that resources be made available online means that Professor Sinnott's specialty, secure targeted information technology solutions for research, is in high demand.

Other presentations also emphasised digital systems, which are a major topic in the data management field of today.

Another very successful session was the Masterchef GCP Masterclass - From sauces to source data? This mouthwatering workshop was (to quote a participant) "elegantly plated, imaginatively prepared and renewed our taste for GCP".

### Hitting the target

The next ASM on the theme of "Hitting the Target" will be on the Gold Coast - see box below. For more information about the ASM and AHRDMA [visit the website](#).



### ALLG and AHRDMA

The ALLG and AHRDMA will be collaborating more in the future, including promoting each others events, and informing members and associates about activities. Professional relationships are very important to the ALLG. If you would like to know more about AHRDMA contact [Adam Stonely](#) and for Victorian regional activities contact [Jess Vinluan](#).



Front row (left to right): **Jessica Roydhouse** (newsletter editor); **Mary Jane Sterry** (ordinary member, 2011 ASM convener); **Jesse Vinluan** (Secretary/ VIC & TAS Regional Coordinator). Back row (left to right): **Adam Stonely** (President/QLD Regional Coordinator); **Paul Newman** (treasurer); **Suzanne Ryan** (Vice-President/NSW Regional Coordinator); **Michelle Jeffrey** (Education Officer). Not in photo: **Rajneet Arora** (Regional Group Coordinator).



### AHRDMA Annual Scientific Meeting

Theme: **Hitting the Target**

**15 – 16 March 2012**

**Q1 Resort and Spa, Gold Coast**

**CALENDAR**

		<b>ALLG event</b>	<b>External event</b>
<b>2011</b>			
October	28-30		Int. Workshop on CLL, Houston
	30 - November 2		HSANZ Sydney
November	8-11	ALLG Scientific Meeting, Brisbane	
	9	SAC meeting, Brisbane	
	10	ALLG AGM, Brisbane	
	10	Board meeting, Brisbane	
	15-17		COSA ASM Perth
	16	Board meeting	
December	10-13		ASH, San Diego
	16	SAC teleconference	
	16	Board meeting	
	16	newsletter published	
<b>2012</b>			
January			
February	6	SAC face to face, Melbourne	
	13	SDMC face to face, Melbourne	
	24	Board meeting	
March	15-16		AHRDMA ASM, Gold Coast
	23	SAC teleconference	
	30	newsletter published	
April	13	Board meeting	
	23	SDMC teleconference	
May	1-4		TROG ASM Darwin
	14-18	ALLG Scientific Meeting, Sydney	
	16	SAC face to face, Sydney	
	17	Board meeting	
June	1-5		ASCO Chicago
	14-17		EHA Amsterdam
	22	SAC teleconference	
	29	newsletter published	

**Board**

**Chair:** Peter Kempen  
**Other independent members:**  
 Geraldine Gray  
 Malcolm McComas  
 John Mortimore  
**ALLG members:**  
 Mark Hertzberg (Chair SAC)  
 Peter Bardy  
 Andrew Roberts  
 Andrew Spencer

**Scientific Advisory Committee**

**Chair:** [Mark Hertzberg](#)  
**Vice Chair** [Pauline Warburton](#)  
[Maher Gandhi](#)  
[Ian Lewis](#)  
[Tony Mills](#)  
[Stephen Mulligan](#)  
[David Ritchie](#)  
[Ken Romeril](#)  
[John Seymour](#)  
[Con Tam](#)  
[Andrew Wei](#)

**Disease Group Chairs:**

**Acute Leukaemia/MDS**  
 Andrew Wei, John Seymour  
**BMT**  
 Ian Lewis, David Ritchie  
**CML/MPD**  
 Tony Mills  
**Myeloma**  
 Pauline Warburton  
**Aggressive NHL/IHL**  
 Mark Hertzberg  
**Low grade NHL/IHL**  
 Stephen Mulligan, Pauline Warburton  
**Supportive Care**  
 Con Tam  
**Laboratory Science**  
 Maher Gandhi

**Representatives**

**Regional:** Pauline Warburton  
**Tissue Bank:** Tony Mills  
**CLLARC:** Con Tam  
**Pathology review:** John Seymour  
**SDMC:** Tony Mills  
**New Zealand:** Ken Romeril  
**Publications:** David Ritchie

The ALLG sponsors trials in malignant haematology in Australia and New Zealand. Trials may be initiated and developed under the auspices of the ALLG or may be international trials, sponsored in Australia and NZ by the group.

The ALLG is open to all clinicians with a special interest in trials in malignant haematology. ALLG members may attend the biannual scientific meetings, receive regular information about activities, and may apply for opportunities for funding for training and other special projects. All ALLG members may participate in any ALLG trial, providing their site is approved for the conduct of ALLG trials and has appropriate facilities.

For further information about joining the ALLG visit the website or contact Dilu Uduwela.

**FUTURE SCIENTIFIC MEETINGS**



**8 - 11 Nov 2011**  
**Hilton Hotel**  
**Brisbane**



**14 - 18 May 2012**  
**Novotel**  
**Brighton le Sands,**  
**Sydney**

**Nov 2012**  
**Hilton-on-the-Park**  
**Melbourne**

**ALLG Operations Office**

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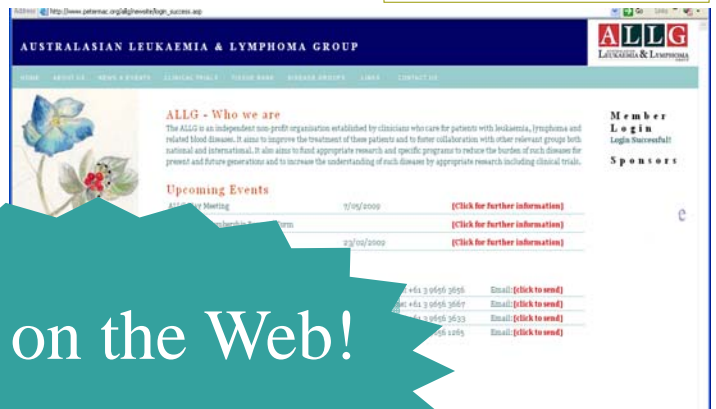
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*(ALLG admin only, no trial faxes)*

**May 2014, Nov 2015,**  
**May 2017**  
**Hilton-on-the-Park**  
**Melbourne**



**We're on the Web!**  
[www.allg.org.au](http://www.allg.org.au)