Better treatments...
Better lives.

ALLG News

Edition 9

ALLG AMLM26 INTERCEPT trial celebrates a milestone achievement – read more inside

ALLG AMLM26 trial team & staff with site study coordinators

Message from the CEO	2
Global Impact of ALLG's Clinical Trials	3
All About Blood Cancer	4
Blood Cancer – Quick Facts	5
Driving Impact for Patients	6
Accelerating our Impact	8
Driving the change needed to accelerate treatments	9
Expanding Access for Patients	10
Behind the Trials	11
Patient and Carer Resources	12

Pictured L-R: Dr Ing Soo Tiong, Dr Sun Loo & Professor Andrew Wei

Message from CEO

Welcome from ALLG Chief Executive Officer

Welcome to the ninth edition of ALLG News. In this edition you can read about Blood Cancer Awareness Month, which takes place annually in September. Blood Cancer Awareness Month is a vital time to raise awareness about the scale and impact of blood cancers like leukaemia, lymphoma and myeloma. You can learn more about ALLG's mission and commitment to ensuring better treatments for patients that create better survival and better quality of life.

Blood cancers can affect anyone, anywhere, at any time, and at any age. Unfortunately there are no screening tests for blood cancers like there are for some other forms of cancer. During Blood Cancer Awareness Month, our goal is to raise awareness of both clinical trial research and the signs and symptoms of various forms of blood cancers.

Blood cancers collectively represent some of the rarest and highest-cost conditions to treat, and there are significant barriers to accessing emerging therapies across Australia and New Zealand, leaving patients at a disadvantage.

ALLG's mission is to improve the treatment and lives of patients with blood cancer by advancing leading-edge clinical trials across Australasia. Through our collaborative network of 1,400+ blood cancer specialists and 98 hospitals, we innovate and collaborate to deliver life-changing research that creates better treatments and better lives, while aiming for cure.

Blood cancer treatments have greatly improved over the years with many new breakthroughs and increases in survival rates – but there is **still so much more to do**. ALLG's clinical trials are researching many new, innovative treatments for patients, including immunotherapies, CAR-T cell therapy and supportive care, that have potential to make a major impact on the standard of care for blood cancer treatments.

An example of a clinical trial that is a major advancement in its design and operations and that will deliver new innovative medicines to patients with acute leukaemia is AMLM26 INTERCEPT. Our AMLM26 INTERCEPT clinical trial for patients with relapsed Acute Myeloid Leukaemia (AML) has received FDA approval to open in the United States at the world-renowned MD Anderson Cancer Center in Texas. This is a major milestone for an Australian-led trial to create this level of reach internationally.

I would like to congratulate AMLM26 Chief Investigator Professor Andrew Wei, the AMLM26 investigator team, and the ALLG trial team led by Amanda Souza, on this major milestone. The front cover of this edition showcases the amazing team that developed and is now leading the day-to-day operations of the AMLM26 INTERCEPT trial. So far, we have 171 patients that have joined the trial at 14 hospitals across Australia. There are five different treatment options available for patients and over the next few months we will expand the number of treatment options and increase participation opportunities at hospitals in Australia and the USA.

Another international achievement is our recent inclusion of Taiwan in the ALLG AMLM22 clinical trial. As part of the activation process for AMLM22, the National Taiwan University Hospital was also activated as a participating as a participating hospital on the ALLG National Blood Cancer Registry (NBCR). The NBCR is a registry that details the clinical pathways of patients suffering with blood cancer to help create better treatments and better lives for patients.

Collaboration with our research colleagues across the across the Asia-Pacific and USA is vital research that meet the priorities of patients with blood cancer. ALLG remains committed to our vision of being Global Leaders with Global Impact and delivering significant scientific outcomes to patients globally.

During Blood Cancer Awareness Month we aim to put a spotlight on blood cancer research and share information about the great work our researchers are doing every day. Please feel free to share your experiences and stories during the month so that together we can keep advancing ways to create *Better Treatments....Better Lives.*

I hope you enjoy this edition of ALLG News.

Yours Sincerely,

Delaine Smith
Chief Executive Officer
ALLG

Global Impact of ALLG's Clinical Trials

The ALLG aims to improve the survival and quality of life of patients with blood cancers by developing and conducting leading-edge clinical trials into the treatment of leukaemia, lymphoma, myeloma and other blood cancers. Results of ALLG trials have contributed significantly to global knowledge of better treatments, generating evidence to change treatment practices in Australasia and globally. We have had five decades of enormous impact through international collaborations with the UK, US, Canada, Asia, and numerous European countries.

Here are just a few highlights of our ALLG leaders' most recent collaborations.

Chief Investigator Professor Mark Hertzberg – The results of the **ALLG HD10** collaborative trial with the German Hodgkin Study Group (GHSG HD21) was published in the high-ranking medical journal 'The Lancet.' This impactful clinical trial showed that the new treatment resulted in better and less toxic treatment, better survival outcomes and improved fertility preservation for patients with Hodgkin lymphoma. HD10's results have set a new benchmark for treating this disease globally.

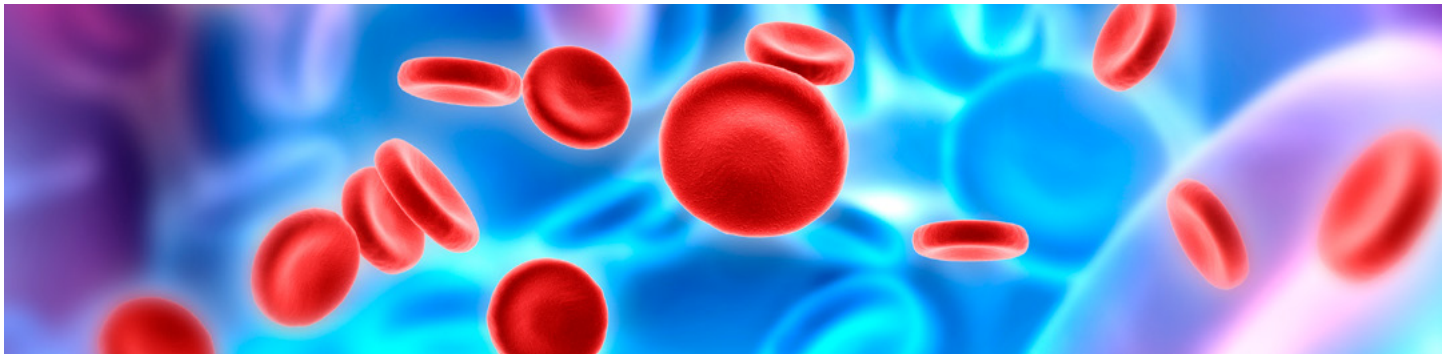
Chief Investigator Professor Hang Quach – The results of **ALLG's MM18** clinical trial, led by Prof Hang Quach, was published in Haematologica (lead author Dr Slavisa Ninkovic). This trial was our first collaboration with the Asian Myeloma Network and established that a combination of carfilzomib, thalidomide and dexamethasone (KTd) was effective in patients with relapsed or refractory multiple myeloma.

Chief Investigator Professor Andrew Wei – ALLG marks a major milestone, with our **AMLM26 INTERCEPT** trial receiving FDA approval to open in the United States at the prestigious MD Anderson Cancer Center in Texas, thanks to the dedication of Prof Wei and the AMLM26 INTERCEPT trial team.

ALLG Chief Investigators Professor Hang Quach & Dr Georgia McCaughan - ALLG's strong collaborations with our Asian Myeloma Network colleagues will result in the **MM26 NORM** platform study opening in a range of countries across Asia during 2024. This innovative study focuses on providing new treatments to groups of myeloma patients who have traditionally been excluded from clinical trials.

ALLG Chief Investigator Associate Professor Matthew Ku - ALLG's first-ever collaboration with the Nordic Lymphoma Group, **ALLG NHL39 Polar Bear,** is bringing a new treatment combination to elderly patients with diffuse large B-cell lymphoma. Elderly patients are often excluded from clinical trials but make up an increasing proportion of patients with this type of lymphoma.

Blood Cancer



All About Blood Cancer

September is Blood Cancer Awareness Month, a global event established to raise awareness and advocate for better research and better treatments for blood cancers. Every year, nearly 20,000 Australians are diagnosed with blood cancer, and over 140,000 are living with blood cancer and receiving treatment.

Blood cancers collectively make up the fourth biggest group of diagnosed cancers in Australia annually, with over 6,000 people dying each year from their blood cancer. Blood cancers are complex, with over 120 different subtypes across leukaemia, lymphoma, myeloma, and others. The impact of particular genes on blood cancers is vital to understanding these cancers.

Types of Blood Cancers

Most blood cancers are uncurable, but early diagnosis can lead to more effective treatment. Some of the more commonly known types of blood cancers are leukaemia, lymphoma and myeloma. These classifications contain many different subtypes of blood cancer.

Leukaemia - Leukaemias are cancers of the white blood cells, which begin in the bone marrow. Leukaemias are grouped by the type of blood cell affected (lymphoid or myeloid) and fast-growing or slower (acute or chronic). The four main types of leukaemia are acute lymphoblastic leukaemia (ALL), chronic lymphocytic leukaemia (CLL), acute myeloid leukaemia (AML) and chronic myeloid leukaemia (CML).

Lymphoma – Lymphomas begin in the lymphatic system and are caused by abnormalities in white blood cells. There are 2 types of lymphoma, Non-Hodgkin lymphoma and Hodgkin lymphoma. The types are classified by how the lymphoma cells look under the microscope. There are many different types of Non-Hodgkin lymphoma that affect either B-cells or T-cells in blood.

Myeloma – Myeloma occurs when abnormal plasma cells of the bone marrow multiply in an uncontrolled way and become myeloma cells. These myeloma cells can produce an abnormal antibody that weakens the immune system and damages kidneys, crowding the bone marrow so there is not enough space to make normal blood cells, and can form tumours in one or many bones of the body. It is referred to as Multiple Myeloma as 90% of people have multiple bone lesions at diagnosis.

Myelodysplastic Syndromes (MDS) – MDS is a group of blood cancers affecting the production of normal blood cells in the bone marrow. It occurs as a result of a mutation in one or more genes of blood cell development, resulting in abnormal growth of blood stem cells.

Myeloproliferative Neoplasms (MPN) – MPN is a group of diseases where the bone marrow makes too many of one or more types of blood cells. The type of MPN is based on whether too many red blood cells, white blood cells, or platelets are being made. This can crowd the bone marrow and interfere with the production of healthy blood cells.

Signs & Symptoms of Blood Cancer

Symptoms of blood cancer can vary but can include:

- Night sweats
- Re-occurring infections
- Pain in bones & joints
- Rashes, lumps, itchy skin, swelling
- Breathlessness
- Frequent bruising & bleeding
- Unexplained weight loss
- Fatigue
- Anaemia

Always consult a doctor if you are concerned about any symptoms.

Blood Cancer – Quick Facts

53 people a day are diagnosed with blood cancer in Australia

There are **no screening processes** or preventative measures for blood cancers

17 people a day in Australia alone **lose their life to blood cancer** every year

Incidence of Blood cancer has **increased by 47%** in the past 10 years and continues to grow

Approximately **140,000 people** are living with a blood cancer in Australia today

By 2035, more than **275,000 Australians** are expected to be living with a blood cancer or blood disorder

Blood Cancer Awareness Month – Key Dates

ALLG and our members work each September to support and raise awareness of blood cancer, and the vital role of clinical trial research in creating better treatments for patients. ALLG continues to pursue research, both locally and globally, to increase survival rates, provide better quality of life and ultimately, find a cure for blood cancers.

SEPTEMBER 1

World CLL Day

Each year, 1000 Australians are diagnosed with Chronic Lymphocytic Leukaemia (CLL) – the most common type of leukaemia diagnosed in Australia. ALLG's member researchers are working on a range of exciting new CLL clinical trials, like the CLL11 Moonshot trial, which uses a new treatment after induction therapy that aims to improve remission depth and outcomes.

SEPTEMBER 4

World Leukaemia Day

Each year, 5,200 Australians are diagnosed with leukaemia. ALLG is committed to increasing survival rates and quality of life for all leukaemia patients. Our world leading AMLM26 INTERCEPT trial is aimed at preventing relapse in patients with leukaemia using new technologies. It's a world-first trial and will have a major impact on the way people are treated now and in the future.

SEPTEMBER 12

MPN Awareness Day

MPN is more commonly diagnosed in people over the age of 50, although it can rarely occur in younger people. New research focuses on the disease modifying the potential of novel drugs, with an attempt to reduce the burden of driver mutations in MPN. The hope is this can translate to lower rates of disease progression and improvement in survival outcomes.

SEPTEMBER 15

World Lymphoma Awareness Day

Each year in Australia, over 7,400 people are diagnosed with lymphoma. The majority are in Non-Hodgkin lymphoma, as either B-cell or T-cell lymphoma. ALLG's NHL35 PACIFIC trial is addressing a new treatment for an uncommon subtype of large B-cell lymphoma (DLBCL) know as primary mediastinal B-Cell Lymphoma (PMBL), which primarily affects young adults.

SEPTEMBER 17

World Patient Safety Day

This is a global initiative focused on prioritising and promoting safer healthcare practices. ALLG is focused on better outcomes for patients and has strong governance in place for our clinical trials, through the independent Safety Data Monitoring Committee, disease Scientific Working Parties and our Scientific Advisory Committee.

SEPTEMBER 20

World ALL Day

Approximately 410 people are diagnosed with Acute Lymphoblastic Leukaemia (ALL) each year. More than half are children and adolescents, although ALL can occur at any age. ALLG's ALL09 SUBLIME clinical trial successfully incorporated a new immunotherapy, blinatumomab, into the treatment for adolescents and young adults (AYA) that increased remission rates and reduced treatment-toxicity.

SEPTEMBER 21

World Marrow Donor Day

World Marrow Donor Day is a day to celebrate stem cell donors that have volunteered to be a stem cell donor for patients in need of a life-saving stem cell transplant. ALLG's BM12 CAST clinical trial for post-transplant patients is assessing a new treatment to prevent graft vs host disease, a side-effect of many transplants.

SEPTEMBER 22

World CML Day

Over 2100 Australians are diagnosed with Chronic Myeloid Leukaemia (CML) every year. ALLG trial leaders have contributed significantly to progressing CML treatments. ALLG trials have introduced novel targeted enzyme inhibitors and molecular techniques that has transformed CML from a fatal disease to one that can be managed through continuous therapy and then treatment-free remission.

SEPTEMBER 24

World Cancer Research Day

World Cancer Research Day is a global day to highlight the importance of cancer research to drive progress in cancer control. ALLG 's members are dedicated to conducting world-leading clinical trial research, with 75+ current clinical trials across leukaemia, lymphoma and myeloma.

Driving Impact for Patients

Brian – ALLG CML9 TIDELL II trial

In May 2008, Brian Mantel received life-altering news that no one ever expects - a diagnosis of Chronic Myeloid Leukaemia (CML). He vividly recalls the shock and alarm he felt, realising that this was a disease he couldn't simply remove with a surgeon's knife. His journey would lead him to Concord Hospital and the compassionate care of Professor Trotman, and a clinical trial that would save his life.

The trial was "simplicity itself", according to Mr Mantel. A prescribed drug of a tyrosine kinase inhibitor, coupled with frequent blood tests and a rapid turnaround of results. "I was extremely fortunate in that I responded exceedingly well to the drug prescribed to me," he said. "Within a matter of weeks, I obtained a 'major molecular response'. This is one of the prime objectives of a CML patient and an indicator of a superior longer-term outcome, though certainly no guarantee.

Brian said, "And the news kept getting better! After some 14 years of maintaining that major molecular response, I asked Professor Trotman if she would allow me to trial a cessation of the tyrosine kinase inhibitor that had, without a doubt, saved my life".

Brian explained that this necessitated some advocacy on his behalf by Professor Trotman with a fellow professor in another medical institution. After some high-level discussion, he was given the green light to proceed on a different trial; a drug-free trial.

Read Brian's full story ***here***

Emma – ALLG HD10 Trial

The ALLG HD10 trial's success was important for younger patients such as Emma, who was only 38 years old when diagnosed in May 2019 with an aggressive Hodgkin lymphoma. By diagnosis, Emma had an 11-centimetre mass (tumour) around her aorta and oesophagus.

After some blood tests and chest X-rays, her GP called her with her test results and said her lymph nodes were up and to go in that day to the emergency department. "The warning bells went off at this point, and I was in a spin," Emma explained. "I never thought it was cancer." Fortunately for Emma, her haematologist and ALLG member A/Prof Matthew Ku suggested that she was eligible for the ALLG HD10 trial.

After two cycles of very aggressive chemotherapy that included seven drug agents, Emma only got nauseous once and slept well, and ate well. By the third week of recovery, she was back to baseline (normal). Emma was then re-scanned, and the haematologist consultant came in with her results after her PET scan and said, with a big smile, 'you are in complete metabolic remission'. Emma said, 'show me the scan!' Nothing had lit up on the scan. Emma did a happy little dance with this great news.

Emma has since brought her trial experience to her role as an ALLG Consumer Representative, to help other patients in this situation.

Read Emma's full story ***here***

Vesselin – ALLG NHL33 Trial

Vesselin Petkov was diagnosed with a rare form of lymphoma called Mantle Cell Lymphoma (MCL). He was one of the first patients to take part in a clinical trial through the Australian Teletrial Program in Cairns – the ALLG NHL33 WAMM trial. Having access to treatment through the teletrial program was life-changing.

Vesselin was able to participate in the clinical trial at his local hospital without being separated from his family. "It meant no more early morning flights, personal expenses, dealing with side effects alone away from the family."

"I chose to enrol in the (NHL33 WAMM) clinical trial because the conventional treatment that was offered to me was 15 years old and while it offered me a chance of remission, it was quite toxic, and all follow up studies showed all patients sooner or later would relapse.

"High quality clinical research is extremely important for the development and approval of new drugs that have the potential to offer better outcomes with less side effects for cancer patients. Clinical trials also offer cancer patients free access to treatments that are not otherwise available."

"My experience with the trial was very positive. So far, I'm in full remission, and I feel really good, and I'm back to work. I feel 100 percent"

Read Vesselin's full story ***here***

Bianca – ALLG ALL09 Trial

Bianca was diagnosed with acute lymphoblastic leukaemia (ALL) in 2020. This news came as a big shock, as she'd only had several symptoms such as weight loss and tiredness. Bianca said, "It was only through a routine blood test for another unrelated health condition when I had to go into the emergency department that they picked up that I had ALL. It then all happened so quickly."

"I was about to start the standard treatment of chemotherapy when the doctor walked in and said, 'wait, there is another option!' and told me about the trial (ALL09). I did have the option of doing conventional treatment, but I read through the clinical trial documents, and it seemed a better option for me." Bianca was sent to Royal North Shore Hospital NSW and began her treatment on ALL09.

"The trial team were the best," Bianca exclaimed. "I was so confident in them. I felt like their golden patient because so many were looking very closely over my treatment."

"I was taking it one day at a time," Bianca said. "I didn't like to look too far ahead but, actually, I felt quite good on the immunotherapy. "It took me a while to get back to work. You still don't know what the future will hold. You do worry it can still relapse, but I feel so lucky I was able to go on that trial.

Read Bianca's full story ***here***

These personal accounts highlight the importance of clinical trials in advancing new treatments, adding to global medical knowledge and providing hope to patients facing the challenge of blood cancer. ALLG sincerely thanks Brian, Emma, Vesselin and Bianca for sharing their stories about participating in ALLG clinical trials.

Accelerating our Impact

Last year, ALLG celebrated our 50th anniversary and five decades of impact in blood cancer. ALLG clinical trials have advanced many treatments for blood cancers and have contributed to what are now standard treatments in many blood cancers.

This momentous anniversary saw the ALLG reflect on **five decades of clinical trials success and impact,** while laying the foundations to accelerate treatments and impact for blood cancer patients.

Results of ALLG trials have shifted the dial, adding to global knowledge of better treatments and changed the way blood cancers are treated around the world. Through international collaborations we have had five decades of enormous impact; for example, more than tripling the survival rates for patients with the Hodgkin and Non-Hodgkin lymphomas.

"The ALLG, the oldest cancer cooperative trials group in Australia and New Zealand, has spent five decades at the cutting-edge of the global development of cures for blood cancer. At 98 hospitals across Australia and New Zealand, more than 14,000 patients have benefited from our clinical trials with extraordinary advances in survival.

"Fifty years ago, most patients with blood cancer died within months. Now, most will have a near normal life expectancy."

Professor Judith Trotman, Chair,
ALLG Scientific Advisory Committee

With 1,400 members across haematology and clinical trial research, and over 180 clinical trials, which now includes cutting-edge platform, precision medicine and CAR-T cell trials, ALLG's story is still being written.

Clinical trials progressing better treatments for better lives

ALLG trials led by our member doctors have contributed widely to understanding the science of blood cancers and driving new treatments. There has been great progress, with clinical trial breakthroughs that have changed the landscape and improved life expectancy greatly for patients.

- In Non-Hodgkin lymphoma (NHL) rates have improved from 45% of people surviving the 5 years after diagnosis to 77% surviving this period.
- Chronic Lymphocytic Leukaemia (CLL) has changed from 49% of patients to 66% of surviving 5 years after diagnosis.
- Multiple Myeloma (MM) has transformed from 28% of patients surviving 5 years or more to 57% surviving 5 years or more.
- Acute Myeloid Leukaemia (AML) has improved from a dismal 15% surviving 5 years, to 53% surviving longer than 5 years.

Driving the change needed to accelerate treatments

ALLG is at the frontline of emerging therapies, with ALLG clinical trials bringing breakthrough treatments to patients across Australia and New Zealand. ALLG provides the network and infrastructure for our member doctors to create, collaborate, and test new ideas, driving innovative research forward for patients.

It's an exciting time in blood cancer treatments. Advances in translational science and genomic screening have transformed the understanding of blood cancers and are making headway in addressing the most devastating and poorly treated blood cancers.

- Genomic screening has transformed the understanding of blood cancers and accelerated a new generation of immunotherapies and precision medicines.
- The potential stem cells offer for treating and potentially curing diseases and disorders with unmet needs is incredible. The technology and science are continuing to progress in this exciting area.
- Breakthrough immunotherapies such as CAR-T cells are being researched and refined in multiple types of blood cancers.
- Innovative platform trials such as AMLM26 INTERCEPT and its precision-medicine based approach are providing targeted, personalised treatments to patients and accelerating the speed of new treatments.
- Machine learning and artificial learning (AI) systems are helping researchers discover promising drug candidates through more efficient data analysis.
- Biobanks have an increasingly important role and are crucial to facilitating future medical research, through correlative studies linked to ALLG trials that power future knowledge and research.
- Consumer representatives continue to provide vital insights into designing clinical trial information for participants and in providing their perspectives for patient centred trial design and conduct.

Clinical trial conduct has grown enormously in sophistication. ALLG is committed to improving the treatment, lives and survival rates of patients with blood cancers through novel trial therapies and designs.

The ALLG will continue to lead a robust and collaborative clinical research program across all blood cancers that drives the best science, evidence and effective outcomes for patients across Australia and New Zealand.

"Patients are at the centre of everything ALLG does. In our 51st year, we remain highly-focused on our mission to create Better treatments and better lives for patients living with all types of blood cancers."

Delaine Smith, ALLG CEO

Expanding Access for Patients

ALLG's Teletrial Program

Teletrials are increasingly being used to enable better access to clinical trials for patients in regional, rural and remote areas of Australia. Teletrials use existing telehealth technology to create a network of clinical trial sites in areas outside of major cities and towns.

ALLG has incorporated teletrials into our clinical trial design and development pathways, to ensure that patients with blood cancer in rural, regional and remote communities have the best possible access to new trials and treatments.

Teletrials mean that both clinicians and trial participants can take part remotely, receiving the best care closer to home.

How do Teletrials Work?

Teletrials create partnerships between lead hospital sites (usually in metropolitan areas) and satellite hospital sites in rural and regional areas. The group of doctors and clinical trial sites work together to deliver the trial to participants under the supervision of the lead site and trial Chief Investigator.

Teletrials use telehealth technology to communicate between the metro and regional sites, and each trial's Chief Investigator supervises Associate Investigators to deliver the best care and trial treatment to patients at their local hospital.

Benefits of Teletrials

- Equitable access to cutting-edge potential new treatments
- Participation in clinical trials and receiving new treatments closer to home
- Reducing time and costs associated with travelling long distances for treatment
- Ability to access local family, community and healthcare support

For more information on teletrials, visit the Australian Teletrial Program (ATP) website at ***https://australianteletrialprogram.gov.au/***

ALLG Teletrials

MM23 SeaLAND

An ALLG phase 3 randomised trial of Selinexor and Lenalidomide versus lenalidomide maintenance post Autologous stem cell transplant for patients with Newly Diagnosed multiple myeloma.

Even with the best available approved agents, myeloma remains an incurable condition with inevitable relapse post initial treatment. Maintenance therapy is now recognised as an important strategy towards prolonging progression free survival and overall survival in the treatment of myeloma.

MM25 Viber-M

A phase Ib/II study of Venetoclax, Iberdomide and Dexamethasone for patients in first or second relapse of Multiple Myeloma with t(11;14).

Treatments called venetoclax and iberdomide have shown improved response rates and progression free survival in relapsed/refractory myeloma. MM25 is assessing a new treatment combination that also includes dexamethasone, that is taken by mouth, for patients with this type of myeloma.

NHL39 POLAR BEAR

R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥80 years, or frail ≥75 years – an open label randomized Nordic Lymphoma Group phase III trial - NLG-LBC7 (POLAR BEAR).

Outcomes for patients with this type of lymphoma have improved markedly over recent years, except for elderly patients. This age group is often excluded from clinical trials but is the group that makes up an increasing proportion of patients with DLBCL.

HD12 CATER-HL

An ALLG phase II study of CHOP And Tislelizumab in Elderly patients with Hodgkin Lymphoma.

HD12 combines an immunotherapy called tislelizumab with chemotherapy in older patients with Hodgkin lymphoma. This new, less toxic treatment will support a greater proportion of older patients being able to access effective therapy for HL.

From Concept to Development

Clinical research is about investigating new treatments for diseases by assessing their relative benefits and effectiveness against existing standard of care. Clinical trials are designed to answer specific research questions that will help establish if the new treatments are better than existing ones and if a new treatment regimen should be introduced more widely.

Safety and Data Monitoring Committee

ALLG's Safety and Data Monitoring Committee (SDMC) is an independent, multi-disciplinary Committee, who review accumulating trial data at specified intervals to monitor the progress of a trial.

The SDMC is responsible for reviewing all new ALLG trials, protocol amendments, and other matters relating to study conduct, patient safety, and trial data quality. Over the course of the last 12 months, they have reviewed 65 ALLG trials in progress and approved 33 protocol amendments to trials.

The SDMC works closely with ALLG's Scientific Advisory Committee to advance and support the ALLG Clinical Trial Program. The SDMC's ongoing periodic trial reviews ensure that the defined treatment and procedures in clinical trials involving human participants are scientifically valid, statistically achievable, and ethically acceptable.

In 2024, ALLG welcomed two new SDMC committee members in 2024, Professor David Curtis and Dr Naranie Shanmuganathan. ALLG appreciates the SDMC Committee for its commitment and dedication to its extensive review of new protocols and ongoing advice.

Key Role - Trial Statistician

The role of a statistician is an important one at all stages of a clinical trial research. Every ALLG trial has a statistician as part of the central trial investigation team and their input and knowledge is vital to ensuring results of trials are able to answer the specific research question of the trial.

Statisticians ensure that the trial design and plan for data collection is appropriate to answer the research question, that the number of patients is adequate to achieve a result, and that the right analysis method is chosen for the type of trial and outcome.

Trial Development Team

Clinical trials are complex, with many planning, governance and activation processes that must be rigorously followed to develop and get a trial ready for participation by patients.

Our Trials in Development and Study Start Up teams work closely together with our ALLG doctors to bring new, innovative research to the clinical trial stage at hospital sites around Australia and New Zealand. They work with clinical trial regulators, ethics and governance teams, trial investigators, hospital teams and other key partners to ensure that ALLG clinical trials can be accessed as quickly as possible by blood cancer patients in need.

Their role is key to driving *Better treatments, better lives* for patients with leukaemia, lymphoma, myeloma and other blood cancers.

Meet the team that makes clinical trials accessible to blood cancer patients (L to R) – Shivani Arora, Project Manager Study Start Up; Jean Chuah, Clinical Research Development Officer; Naomi Sprigg, Operations Manager; and Tracey Gerber, Business Development Manager.

Patient and Carer Resources

As the only non-profit collaborative clinical trials group in Australia and New Zealand for blood cancers, ALLG has the capability to run independent doctor-led clinical trials in Australasia and, crucially, to participate in international trials. This ensures opportunities for better treatments today for Australian and New Zealand patients that they would not otherwise have access to. You can learn more about clinical trials and what they involve, by visiting our website's ***Frequently Asked Questions*** page. If you are a loved one has blood cancer, speak with the treating doctor about participating in an ALLG clinical trial.

There are many places and people available for patients to find out about clinical trials.

1. Your hospital's clinical trial site team and Principal Investigator (Haematologist)
2. The ALLG's website – as sponsor of clinical trials in blood cancer (ALLG or pharmaceutical company) and individual trial Patient Information and Consent Forms
3. WHO approved 'Register' for clinical trials; Australian Clinical Trials website – ANZCTR
4. Patient support networks e.g. Cancer Council Australia, Leukaemia Foundation, Lymphoma Australia, Myeloma Australia

Click on the logos and titles to link to websites

ALLG

– Frequently Asked Questions about clinical trials

– Latest ALLG clinical trials

Australia and New Zealand Clinical Trials (ANZCTR)

Leukaemia Foundation Australia

Leukaemia & Blood Cancer New Zealand

Lymphoma Australia

Myeloma Australia

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