

<b>ALLG Trial Number:</b>	CLL07
<b>Trial Name:</b>	An Australasian, phase II, multicentre, randomised, study investigating efficacy and safety for dose reduced fludarabine, cyclophosphamide and i.v. obinutuzumab (G-FC3) versus oral chlorambucil and i.v. obinutuzumab (G-Clb) in previously untreated, comorbid (CIRS score $\geq 6$ ), elderly ( $\geq 65$ years old) patients with chronic lymphocytic leukaemia (CLL)
<b>Lay Summary:</b>	Treatment for CLL has improved in recent years but many elderly and sick patients cannot tolerate these treatments. Rituximab is a monoclonal antibody treatment that kills the leukaemia cells by targeting a marker on the outside of the cell. An earlier clinical trial run by the ALLG has shown that rituximab was well tolerated when given together with low doses of usual chemotherapy treatment in elderly patients. The CLL07 clinical trial continues this research using a new monoclonal antibody, similar to rituximab, known as GA101 that has been shown to kill cancer cells more effectively than rituximab. Patients will be given GA101 together with one of two types of low dose chemotherapy combinations used in CLL treatment. The type of low dose chemotherapy treatment will be assigned by chance (randomisation). Patients on this trial will receive 6 cycles of chemotherapy and GA101, and remaining disease will be measured in a similar way to patients that are not on the clinical trial. The outcome of the study will be mainly measured by the number of side effects that patients experience while having treatment, but the response of the CLL disease will also be taken into account.
<b>Participating Hospitals:</b>	1. Border Medical Oncology / 2. Flinders Medical Centre / 3. Geelong (Barwon Health) / 4. Nepean / 5. Royal Hobart / 6. Royal North Shore / 7. Sir Charles Gairdner / 8. St George / 9. Sydney Adventist / 10. Western Health / 11. Westmead
<b>Target Accrual (International):</b>	n/a
<b>Target Accrual (ALLG):</b>	120
<b>Expected Final Accrual Date:</b>	September 2018