



Trial Information Summary

ALLG Trial Number:	CML12
Trial Name:	A single arm phase II study to individualize dasatinib dosing based on trough levels and molecular response to maintain efficacy whilst minimising toxicity
Lay Summary:	Dasatinib is a highly effect agent for treating chronic myeloid leukaemia in preventing disease progression and prolonging survival. However, a number of patients treated with this drug get side effects. Pleural effusion, or fluid around the lungs in the chest cavity, is a side effect associated with dasatinib treatment of particular concern and may occur in up to 40% of elderly CML patients treated with this drug. We suspect patients with higher dasatinib blood levels are more likely to get side effects. In the DIRECT study, we will measure drug levels and lower a patient's dasatinib dose to minimise pleural effusions. At the same time, we will also do blood tests (BCR-ABL QPCR) to ensure the leukemic cells are being killed effectively.
Participating Hospitals:	1. Austin Health / 2. Calvary Mater Newcastle / 3. Concord / 4. Flinders Medical Centre / 5. Geelong (Barwon Health) / 6. Gosford / 7. Liverpool / 8. Princess Alexandra / 9. Royal Adelaide / 10. Royal Hobart / 11. Toowoomba / 12. Westmead
Target Accrual (International):	N/A
Target Accrual (ALLG):	80
Expected Final Accrual Date:	October 2018