AUSTRALASIAN LEUKAEMIA & LYMPHOMA GROUP	**Trial Information Summary**

ALLG Trial Number:	**APML5**
Trial Name: A phase I pharmacokinetic evaluation of oral arsenic trioxide in previously untreated patients with acute promyelocytic leukaemia	
Lay Summary: Acute promyelocytic leukaemia (APL) is a unique subtype of acute myeloid leukaemia. It is characterized by marked responsiveness to all-trans retinoic acid, arsenic trioxide (ATO) and idarubicin chemotherapy. Recent studies indicate long-term remission (and therefore probable cure) can be achieved in over 90% of patients when these drugs are used. Although ATO is the most active single agent in the treatment of APL, its use is cumbersome because it must be given by a 2-hour infusion on a daily basis for several weeks at a time. An oral formulation would dramatically simplify treatment for patients, and would considerably reduce health care resource utilisation. An oral formulation might also be less toxic than intravenous ATO. The current proposal is to study a newly developed ATO capsule for oral use. We will compare it with the standard intravenous form of ATO by measuring blood levels of ATO given orally and intravenously at multiple time points during treatment. We anticipate that this will allow us to calculate the correct oral dose for treating APL more simply, more efficiently, and more safely.	
Participating Hospitals: 1. Royal Prince Alfred	
Target Accrual (International):	n/a
Target Accrual (ALLG):	28
Expected Final Accrual Date:	December 2018