

TIGER Trial News

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Welcome to our second TIGER newsletter

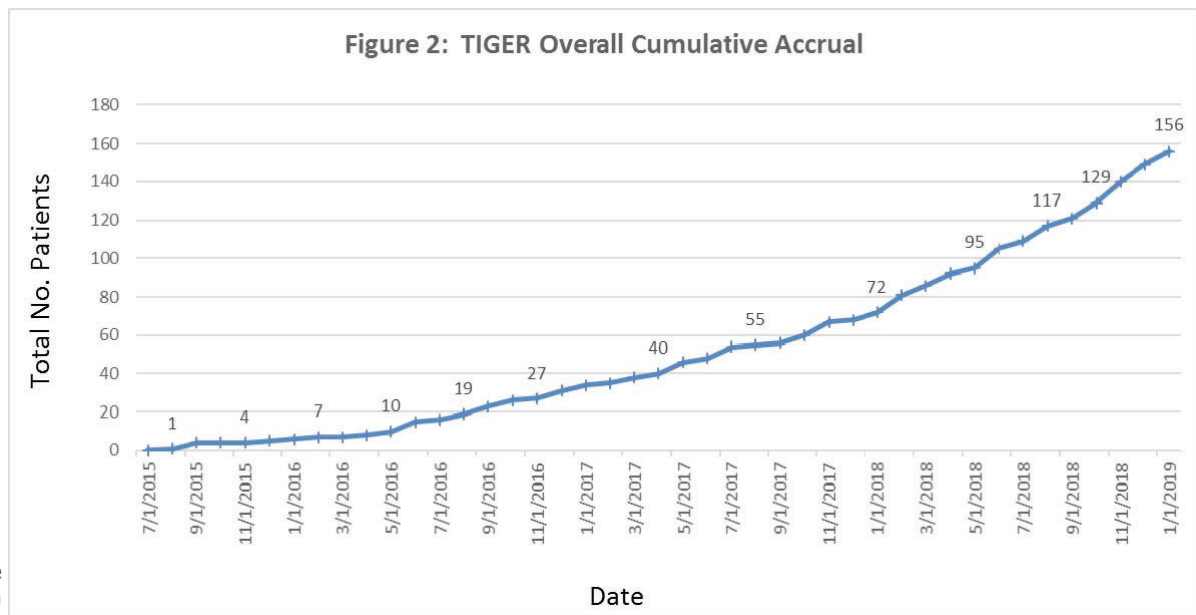
We are pleased to report we have activated all four Australian sites for Tiger with Peter MacCallum Cancer Centre coming on board in October 2018.

We have had a great start to recruitment with three patients randomised across ANZ sites. Current global recruitment is at 156 patients which is 37% of its global recruitment target. Thank you all for your hard work and dedication, we look forward to the milestones 2019 will bring.

Global recruitment

Globally, the study has enrolled 156 patients since opening in 2015; 70 patients recruited in Europe; 83 in North America and 3 in Australia.

This chart shows the cumulative and monthly accrual rate across the 87 sites open in the US, Europe and Australia.

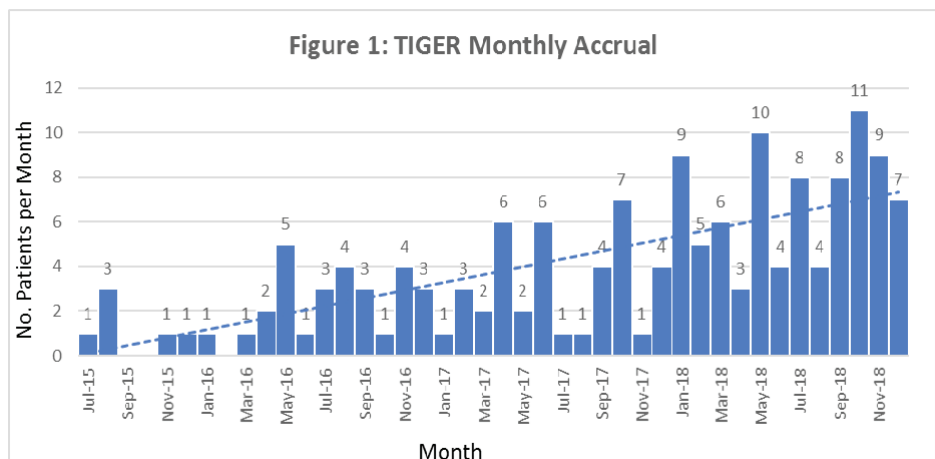


*Graphs are courtesy of the Alliance of Clinical Trials in Oncology in Chicago

Current local recruitment

3 out of 4 sites recruited their first patient within 5 months of study activation which is a great achievement. If your site is experiencing specific barriers to recruitment, or have any questions regarding eligibility, please contact us at: tiger@ctc.usyd.edu.au.

Site	Patients
Chris O'Brien Lifehouse	1
Peter MacCallum Cancer Centre	1
Princess Alexandra Hospital	1



Hot Tips and data management



Patient registrations are conducted using OPEN as outlined in the Registration Procedures section of the protocol and in the OPEN tab of the CTSU website. Please remember to send through confirmation of randomisation to the TIGER mailbox: tiger@ctc.usyd.edu.au

SAE reporting needs to be completed within 24 hours of site awareness. Details to be uploaded onto CTEP-AERS. Each report will need to be signed off by a study investigator. Once submitted, confirmation of submission will be emailed to site and a 'Ticket Number' will be provided. Please remember to notify the TIGER study team of the SAE, and send through the ticket number within 24 hours to the TIGER mailbox: tiger@ctc.usyd.edu.au.

iMedidata RAVE and CTEP reminder

- A reminder to sites to complete all patient data in iMedidata RAVE. Supporting documentation requires uploading the patients baseline; off treatment visit; and if there's a new primary (section 6.1.1 of protocol)
- Investigators and site staff, need to ensure their CTEP account is renewed annually. The NHMRC Clinical Trials Centre will send reminders and assist you through this process. Please contact the TIGER mailbox if you have any questions regarding your account.



Protocol Amendment

Protocol V8.0 (dated 13Aug2018) was approved by the lead HREC (SLHD – RPAH zone) on 23Jan2019. If you have not done so already, please submit this version to your local governance and forward through the approval once received.

Message from the Lead PI Darren R. Feldman, MD of Memorial Sloan Kettering Cancer Centre in New York

..The TIGER trial is going to help patients into the future and their carers irrespective of the results, as it will define the standard of care for second-line treatment in this disease. A positive trial will underpin the role of high dose chemotherapy (HDCT) (TI-CE) by helping our patients live longer. A negative trial will allow us to spare some patients from significant toxicity associated with HDCT. It's also possible, due to the size of the study, that we could pursue a risk-tailored approach in the future, as in the first-line setting.

Once again, I would like to extend my deep appreciation for all of your hard work this past year(s) to make this study a success.. I am confident that we will finish this trial in due course and that the trial is robust enough to address the most important question in testis cancer.

TIGER key contacts

Clinical trial operations: tiger@ctc.usyd.edu.au

Sponsor queries (payments, contracts) Margaret McJannett E: anzup@anzup.org.au

Coordinating PI (ANZ): A/Prof Peter Grimison E: peter.grimison@lh.org.au

Trial pages: <https://anzup.org.au/content.asp?page=trials-tiger>

ANZUP ClinTrial Refer app available for download from iTunes and Google Play

UPCOMING EVENTS

Germ Cell Concept Development Workshop

Tuesday, 30 April 2019

Peter MacCallum Cancer Centre, Melbourne

Concept submission deadline: Tuesday, 9 April 2019



ANNUAL SCIENTIFIC MEETING
21-23 JULY 2019 • HILTON, BRISBANE

