

TheraP Trial News

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Welcome to the first TheraP newsletter

TheraP opened its first site, Peter MacCallum Cancer Centre on 29 January 2018, followed by Royal Brisbane and Women's Hospital in February, St Vincent's Hospital Sydney in March and Moorabbin of Monash Health in April. Another six sites are completing activation and local approval processes and are expected to open in the coming months. Peter MacCallum were first to recruit, with St Vincent's and Royal Brisbane and Women's hospitals close behind. Congratulations to teams at these sites for the great start to recruitment!

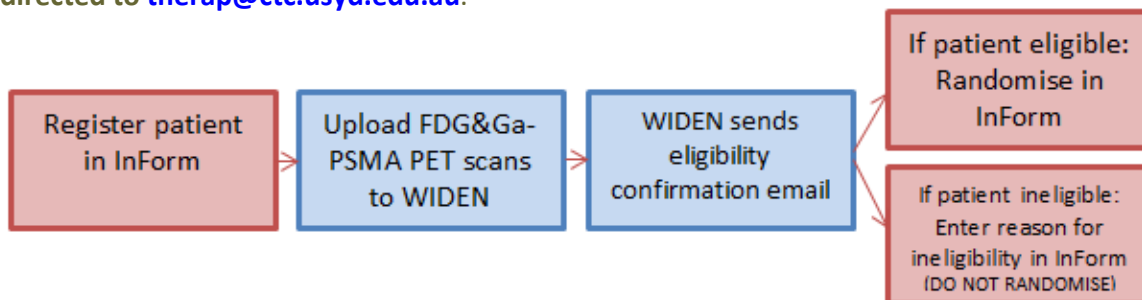
Patient registration and randomisation process

The TheraP patient enrolment process commences with patient registration in InForm, which should be performed only following informed consent. An email will immediately confirm whether registration has been completed. Completion of InForm registration will trigger the addition of the patient in the WIDEN system, enabling nuclear medicine staff to upload FDG-PET and Ga-PSMA PET scans. These scans will then be reviewed and the result of this review (eligible or not eligible) will be provided by email to site staff.

If the WIDEN email confirms the patient MEETS the inclusion criteria then you can proceed with randomisation in InForm, ensuring the patient ID and date of birth correspond. You will need to enter the 'Number of disease sites' from the WIDEN email into the RANDDETAILS form in InForm.

If the WIDEN email states that the patient DOESN'T MEET the inclusion criteria then DO NOT proceed with randomisation. Please enter the reason for ineligibility in the RANDDETAILS form in InForm, ensuring that the patient ID and date of birth correspond with the email. The reason for ineligibility is included in the WIDEN email. Please refer to the eCRF Completion Guidelines (v1.2) for full details.

Questions relating to InForm, WIDEN user accounts and WIDEN eligibility emails should be directed to therap@ctc.usyd.edu.au.



TheraP is a partnership between ANZUP and the Prostate Cancer Foundation of Australia (PCFA)



in collaboration with CTC



LuPSMA proof of concept results published in The Lancet Oncology

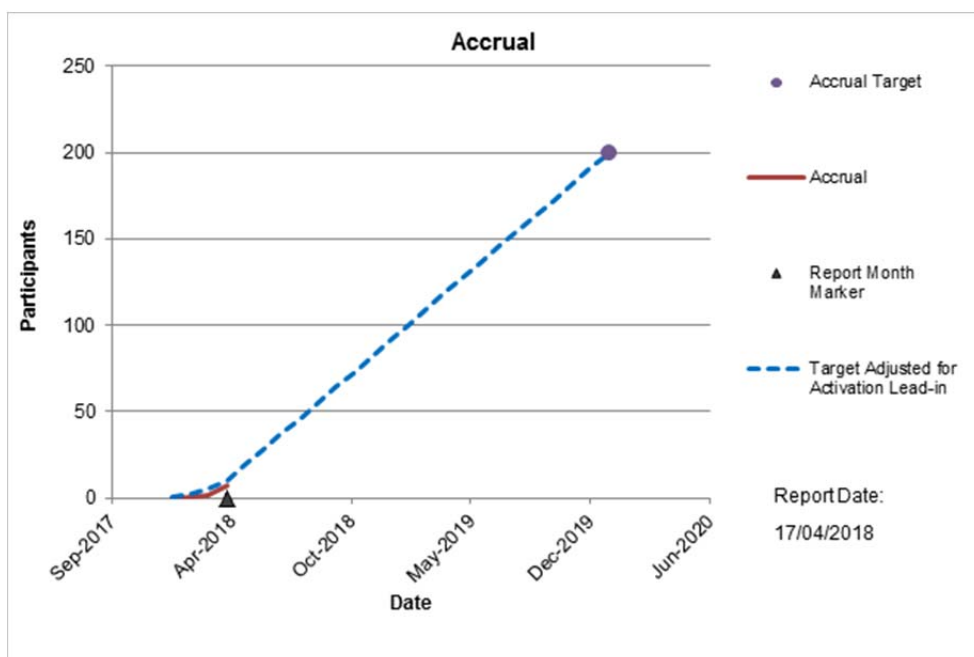
Results of Prof Michael Hofman's Phase II, single-arm study which led to the ANZUP/PCFA TheraP trial have now been published online in *The Lancet Oncology*: [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(18\)30198-0/fulltext](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30198-0/fulltext)

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Current recruitment

To date, 20 patients have been registered, of which 11 have been randomised and 5 have failed post-registration screening. We hope to see the remaining six sites commencing recruitment soon.

Please let CTC know via the trial email (therap@ctc.usyd.edu.au) if you experience any barriers to recruitment as it is important to address these as early as possible.



Active sites	Activated	Patients registered	Patients randomised	Post-registration screen failures
Peter MacCallum Cancer Centre	29 Jan 18	6	5	1
Royal Brisbane and Women's Hospital	20 Feb 18	4	2	2
St Vincent's Hospital Sydney	13 Mar 18	10	4	2
Monash Moorabbin Hospital	5 Apr 18			
Total	4	20	11	5

The following will be requested at the beginning of the month:

- Updated screening log. Please provide accurate screen failure reasons to help us trend any barriers to recruitment.
- Translational research blood collection forms collected in the last month.
- Quality of life forms collected in the last month.



Please send copies of the above to therap@ctc.usyd.edu.au.



TheraP key contacts

- Clinical trial operations, CTC E: therap@ctc.usyd.edu.au and kate.ford@ctc.usyd.edu.au
- Sponsor queries (e.g. site payments, contracts) E: simran.chawla@anzup.org.au T: +61 2 8036 5271
- Coordinating PI: Michael Hofman E: michael.hofman@petermac.org
- Trial pages: <https://www.ctc.usyd.edu.au/our-research/clinical-trials/trial-pages-login.aspx> (log in required) here you will find downloadable copies of all study documents and tools.
- ANZUP ClinTrial Refer app available for download from **iTunes** and **Google Play**

