

TheraP Trial News

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Recruitment closed – CONGRATULATIONS!

A huge Thank You and Congratulations to everyone for your incredible contribution to reaching the 200 patient recruitment target for TheraP! The final patient was randomised on Tuesday 10 September at Peter MacCallum Cancer Centre, four months earlier than expected.

Special congratulations to the teams at Peter MacCallum who finished as our lead recruiter with 31 patients randomised, closely followed by St Vincent's Sydney with 28 patients and Royal Brisbane & Women's with 26.

Analysis preparation

With the final patients now enrolled, preparations have commenced for the first analysis later this year. In order to meet analysis deadlines, please ensure that you keep up to date with InForm data entry as follows:

- **Data entry within 2 weeks following each visit**
- **Queries addressed within 2 weeks**

If you have any difficulties keeping to these timelines, or any questions regarding data entry or queries then please get in touch with therap@ctc.usyd.edu.au as soon as possible.

PICF amendment

We recently received HREC approval for a PICF amendment and Addendum to correct an error in the follow up schedule. Please send your site specific versions to therap@ctc.usyd.edu.au for review prior to RGO submission if you haven't already.

All TheraP participants must be re-consented to the PICF Addendum, with the following exceptions:

- PET screen failed patients
- Patients on 12-weekly follow ups who did not attend any 4-weekly follow ups

On receipt of RGO approval, the TheraP team will provide you with a list of the patients requiring re-consent at your site.

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

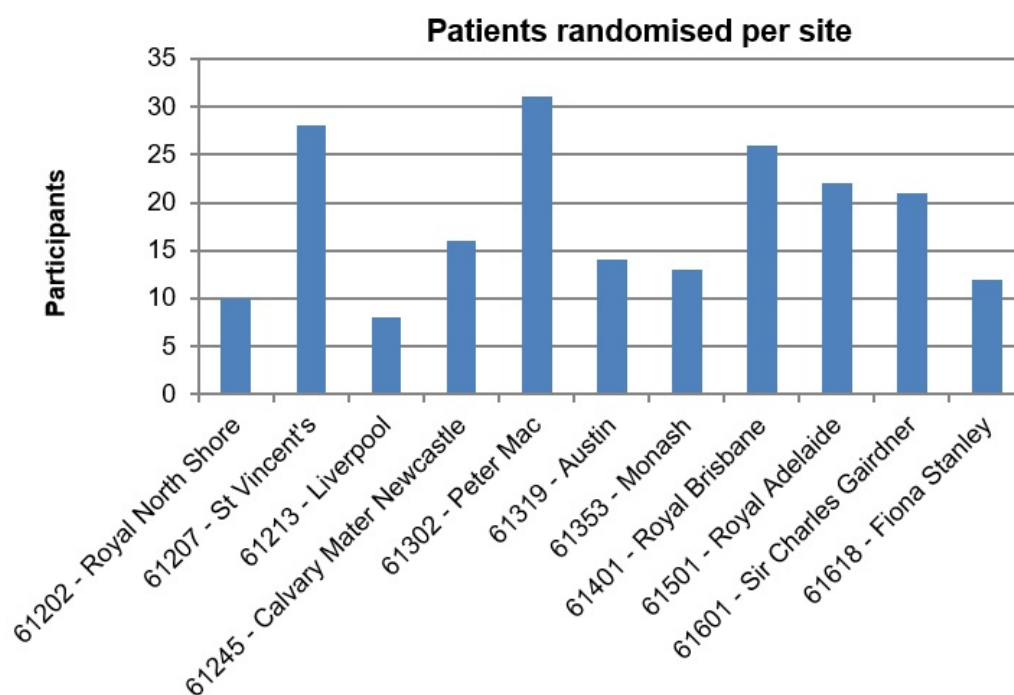


This study is an investigator initiated collaborative group study led by ANZUP Cancer Trials Group in collaboration with the NHMRC CTC.



Funding and support from





Follow up of PET screen-failed patients

Please continue to complete the 6-monthly follow up of patients deemed ineligible on screening PETs. There are currently a number of overdue and missing screen-fail follow up visits in the database.

Patients originally consented to PICF v1.0 should have been re-consented to the Ineligible patient PICF to allow collection of this follow up data.

Please let the TheraP team know at therap@ctc.usyd.edu.au if any patients are not willing to consent to this follow up, or if you have any queries regarding this process.

WIDEN uploads and scan reports

Thank you to all the teams who have been uploading CT, WBBS and SPECT/CT scans to WIDEN. Please keep up the good work! We'll be sending another round of due uploads shortly.

Thanks also to all the Study Coordinators who have been sending through the CT and WBBS scan reports. As we approach analysis over the coming months, it will be particularly important to ensure that all of these scan reports have been provided to CTC.

Recording deaths in InForm

When entering death details in InForm, please ensure that you complete all the required forms:

- If the patient is on treatment
 - Record the death as a grade 5 fatal SAE
 - Complete the 'DTH' form to provide date and cause of death
 - Complete the 'EOS' visit
- If the patient is in follow up
 - Add a new follow up visit and select 'Dead' for patient status
 - Complete the 'DTH' form to provide date and cause of death
 - Complete the 'EOS' visit

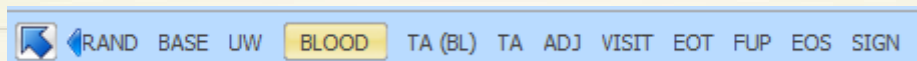
Translational research

RESEARCH BLOOD COLLECTION TIMEPOINTS

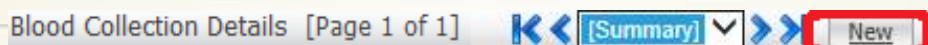
- Collect Translational Research (TR) bloods from **all participants** at:
 - Cycle 1 Day 1 (Baseline)
 - Cycle 3 Day 1 (Lu-PSMA arm) (week 13 day 1) **or** Cycle 5 Day 1 (cabazitaxel arm) (week 13 day 1)
 - **At first progression (PSA or radiological) (before starting subsequent therapy)**
- **TIP** If TR blood was not collected at the scheduled timepoint, collect at the next clinic visit.
- **Progression bloods** can be collected at any time before starting subsequent therapy.
- Bloods for **PSA progression** should not be collected until PSA progression is **confirmed** by a second reading 3 weeks after the initial reading.

RESEARCH BLOODS – DATA

- **Enter** all TR blood collections into InForm:
 - Enter **every TR blood collection** in the **BLOOD** visit



- Click **New** (far right) to create the form for each TR blood timepoint



- **Email** the completed blood collection form **in real time** to therap@ctc.usyd.edu.au
- **TIP** If a TR blood timepoint is missed (and will never be collected), go to the blood form in InForm, answer "Was blood collected and processed at this timepoint according to the protocol?" as No and provide the reason in the free text box.

ACTION REQUIRED

- **Please complete** all outstanding InForm entries and **email** all outstanding blood collection forms to therap@ctc.usyd.edu.au
- **Please ensure** bloods are collected at **first progression (PSA or radiological)** (before starting subsequent therapy)

Thanks again to everyone for your ongoing support for the TheraP trial. As always, please don't hesitate to get in touch at 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
- Coordinating PI: Michael Hofman E: michael.hofman@petermac.org
- Sponsor queries (payments, contracts) Margaret McJannett E: anzup@anzup.org.au
- 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](#)

