

# TheraP Trial News

[www.anzup.org.au](http://www.anzup.org.au)

## Welcome to the third TheraP newsletter

Welcome to our first TheraP newsletter of 2019. Recruitment continues to track ahead of schedule with 70% of the target 200 patients now randomised. Thank you to everyone for your ongoing commitment to the trial.

## Follow up of PET screen-failed patients

As part of the TheraP protocol v2.0 amendment, patients screen-failed on the PSMA & FDG-PET scans are to be followed up every six months.

- Patients screen-failed prior to local approval of protocol v2.0 must first be re-consented to the TheraP Ineligible patient PICF
- Patients screen-failed after local approval of protocol v2.0 do not need to be re-consented (i.e. patients who consented to the local version of master PICF v2.1)
- For patients who passed away prior to local approval of the amendment, please provide details of the death and any treatments commenced following TheraP screen failure. An HREC waiver was provided for collection of these details.

**For sites which haven't already, please commence this re-consent (where applicable) and six-monthly follow up of PET screen-failed patients.**

## Follow up schedule

There has been some confusion regarding the follow up schedule for patients at various stages of PSA and radiological progression.

**To clarify, the 'Post progression follow-up' schedule of 12-weekly survival follow ups should only be commenced once a patient has confirmed RADIOLOGICAL progression.**

Please refer to the attached flow chart for further clarification.

## Collection of CT and bone scan reports and RECIST worksheets

We have now started collecting CT, bone scan reports and RECIST worksheets for all randomised TheraP patients.

Please send reports and worksheets through to [therap@ctc.usyd.edu.au](mailto:therap@ctc.usyd.edu.au) and ensure that all documents are de-identified prior to sending. Going forward, you will receive a monthly report on any outstanding reports along with a report on CT/WBBS/SPECT scans overdue for WIDEN upload.

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



**Prostate Cancer Foundation of Australia**

*ANZUP is collaborating with NHMRC CTC to conduct the TheraP study.*



NHMRC  
Clinical Trials Centre

*Funding and support from*



Australian Government

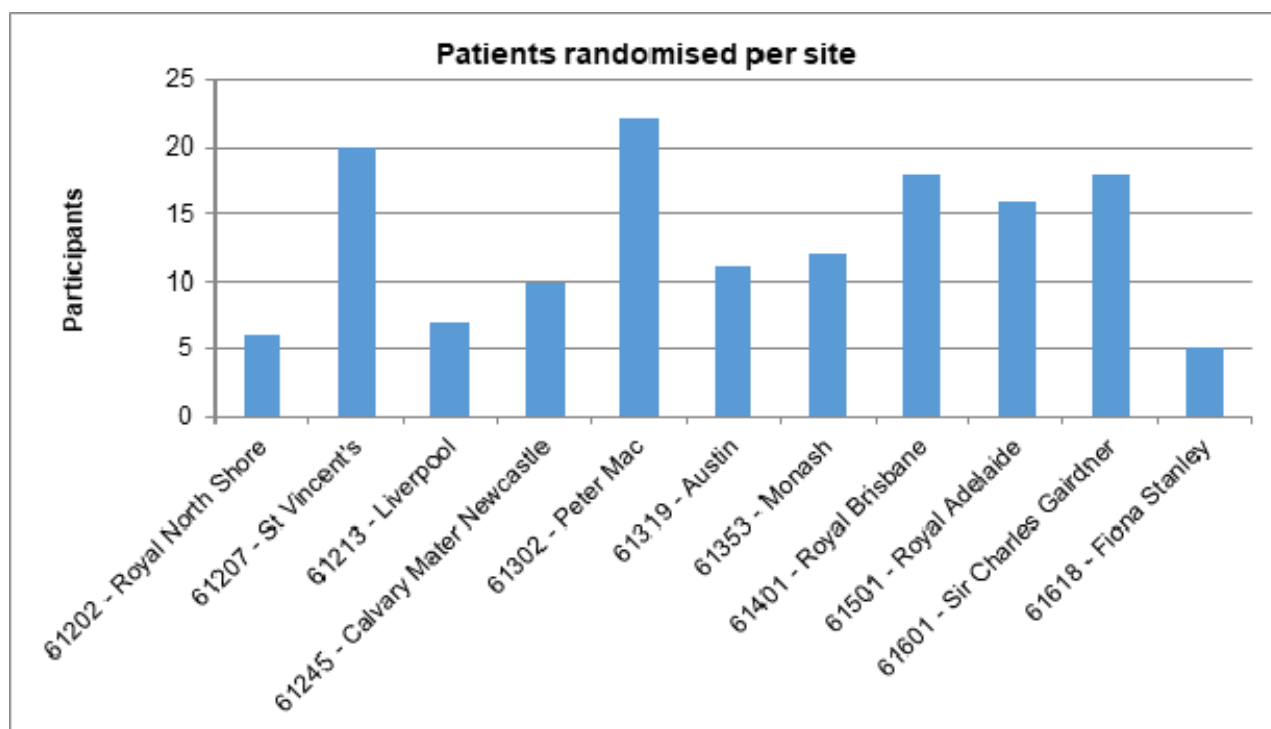


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## Study update

Peter MacCallum and St Vincent's remain the top recruiters with 22 and 20 patients randomised respectively.

### 145 patients randomised

- 72 Lu-PSMA patients
- 73 Cabazitaxel patients

61 screen failed patients on FDG/PSMA-PET.

## PSA progression

There has been some confusion regarding PSA progression when the upward rise in PSA is not straight forward. Please refer to the attached guidance sheet for assistance in determining and entering the data for PSA progression.

## Preventing cabazitaxel arm withdrawals

Please continue to ensure that adequate discussion is had with patients during screening to confirm that they are committed to cabazitaxel treatment, if randomised to that arm.

As we are using an intention to treat analysis to minimise bias, patients withdrawn after randomisation cannot be replaced and thus impact on the statistical power of the trial.

**If you have any concerns that a patient may withdraw from the trial if randomised to cabazitaxel then they should not be enrolled.**

## UPCOMING EVENTS

### Prostate Concept Development Workshop

Friday, 17 May 2019  
 Pullman Sydney Airport, 191 O'Riordan Street, Mascot, NSW  
 Concept submission deadline: Friday, 26 April 2019



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



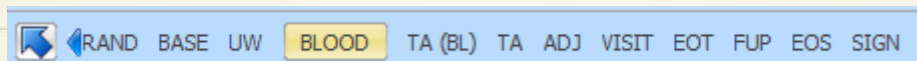
## Translational research update

### RESEARCH BLOOD COLLECTION TIMEPOINTS

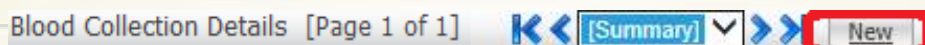
- Collect Translational Research (TR) bloods from all participants at:
  - Cycle 1 Day 1 (Baseline)
  - Cycle 3 Day 1 (Lu-PSMA arm) (week 13 day 1) **or** Cycle 5 Day 1 (cabazitaxel arm) (week 13 day 1)
  - **At first progression (PSA or radiological) (before starting subsequent therapy)**
- **TIP** 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](mailto: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](mailto:therap@ctc.usyd.edu.au)
- **Please ensure** bloods are collected at **first progression (PSA or radiological)** (before starting subsequent therapy)

**Thank you from the TheraP team!**

### TheraP key contacts

- Clinical trial operations, CTC E: [therap@ctc.usyd.edu.au](mailto:therap@ctc.usyd.edu.au) and [kate.ford@ctc.usyd.edu.au](mailto:kate.ford@ctc.usyd.edu.au)
- Coordinating PI: Michael Hofman E: [michael.hofman@petermac.org](mailto:michael.hofman@petermac.org)
- Sponsor queries (payments, contracts) Margaret McJannett E: [anzup@anzup.org.au](mailto: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](#)

