ANZUP 1603

ANZUP Cancer Trials Group Limited

TheraP Trial News

www.anzup.org.au

First data analysis complete – THANK YOU!

A massive thank you to all the Study Coordinators, Data Managers and Investigators for your incredible work in answering queries and getting the data ready for analysis through December and January. We are pleased to say that the ASCO abstract was submitted in February.

Further analyses are planned through 2020 so please keep entering data within two weeks following each patient visit, and ensuring that open queries are answered as soon as possible.

If you have any questions regarding data entry or queries then please get in touch with **therap@ctc.usyd.edu.au**

CT and WBBS scan reports and WIDEN uploads

In preparation for the next analysis, the CTC clinical team will shortly be reviewing CT and bone scan reports to adjudicate radiological endpoints.

The wonderful TheraP trials assistant Kathleen Harwood regularly provides sites with lists of overdue scan reports and WIDEN uploads. Please urgently upload any outstanding scans to WIDEN and send any overdue scan reports to the **therap@ctc.usyd.edu.au** mailbox for clinical team review.

Monitoring Findings

A few Medical Oncology and Nuclear Medicine teams still have monitoring findings to action. If this applies to your team then please get in touch with **therap@ctc.usyd.edu.au** for assistance in closing out the final few items.

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

Prostate Cancer Foundation of Australia

Funding and support from

Australian Government
ansto
Nuclear-based science benefiting all Australians
ENDOCYTE
QANTASLINK
IT'S A BLOKE THING
MOVEMBER FOUNDATION
Distinguished Gentleman's Ride

Help! PCWG3 is too complicated!

Assessing progression of bone lesions by PCWG3 can be tricky, but the following set of questions may help. You can also contact **therap@ctc.usyd.edu.au** to talk through any cases which you're unsure on.

PtID: _____ Date of bone scan: _____

1. Are there 2 or more new lesions compared to the week 11 scan?

◯ **Yes** ◯ **No**

If Yes, proceed to question 2.
If No, the patient does not have radiological progression by PCWG3 on bone scan.

2. Is this the first scan performed POST the week 11 scan?

◯ **Yes** ◯ **No**

If Yes, proceed to question 3A.
If No, proceed to question 3B.

3A. Were there 2 or more new lesions at the WEEK 11 scan compared to the BASELINE scan?	3B. Does this scan confirm the presence of 2 or more new lesions seen since the WEEK 11 scan?
◯ **Yes** ◯ **No**	◯ **Yes** ◯ **No**

If Yes, patient has met criteria for radiological progression by PCWG3 on bone scan.
If No, the patient does not have radiological progression by PCWG3 on bone scan.

(adapted from Scher et al. 2016)

To summarise, if two new bone lesions are seen on the week 11 scan then the next scan must show another two new lesions in order for PCWG3 progression criteria to be met.

If two new bone lesions are seen from the week 23 scan onwards, then the subsequent scan must just confirm that those two new lesions are still present in order to meet PCWG3 progression criteria (another two new lesions are not required).

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

Translational research

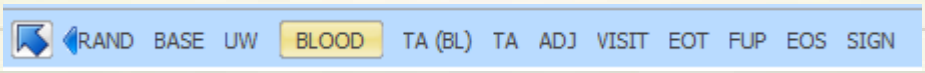
RESEARCH BLOOD COLLECTION TIMEPOINTS

- 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)**

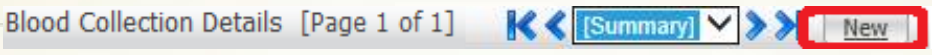
- **TIP** If TR blood was not collected at the scheduled timepoint, collect at the next clinic visit.
- **Progression bloods** can be collected at any time before starting subsequent therapy.
- Bloods for **PSA progression** should not be collected until PSA progression is **confirmed** by a second reading 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/trial-pages/
  (log in required) here you will find downloadable copies of all study documents and tools.