

TheraP Trial News

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STUDY UPDATE

HOT OFF THE PRESS! *The TheraP Biomarker abstract has been accepted as an Oral presentation at ASCO GU 2022! Congratulations to all involved!*

Greetings from the TheraP team! We hope everyone is keeping safe and well as we head into the end of 2021 and welcome in the new year. Hopefully you have a chance to unwind with some well-deserved time off over the holiday period. TheraP will officially finish follow-up on 31 December 2021 and commence close-out procedures in 2022.

We would like to extend a very big thank you to everyone that has worked so hard on the TheraP study for the last few years. It would not have been such a great success without all of the site teams. As the first trial in the world comparing Lu-PSMA to an active and effective treatment, TheraP is a very important study which will continue to advance research in theranostics and prostate cancer long after it is over.

In fact, in February 2021, the TheraP trial achieved their first major publication with an article published in The Lancet. Congratulations to Prof Hofman and the TheraP team!
 The article can be [found online here](#).

Follow-up Data Collection: Overall Survival & Survival Sweep

Thank you to all site staff for your ongoing efforts to complete follow up visits and data entry to date. Please continue to complete visits up to and including **31 December 2021** for all participants currently in follow up.

Additionally, survival status **as of 31 December 2021** is required for all participants for end of study data analyses. We ask that you please confirm and update survival status at your earliest convenience in 2022, as this data will be required for an ASCO abstract submission in February 2022.

Reminder: Overall Survival data is required for all randomised participants and screen fail patients who consented to follow up data collection. Your assistance is greatly appreciated. All other follow up data collection can be ceased after 31 December 2021 (with the exception of one participant, who is undergoing re-treatment).

For any questions, please contact TheraP.study@sydney.edu.au.

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



Funding and support from



Closeout

With follow up data collection ending after 31 December 2021, the TheraP team will begin contacting sites to commence formal site closure procedures in the beginning of 2022.

To assist in ensuring this process is as quick and easy as possible, please ensure all study documentation (including eCRF entries) are up to date, complete and ready for archiving. This includes:

- All eCRF entries – this will ensure all site payments will be up to date and final.
- Essential document checklist (EDC) – please ensure all essential documents are up to date and complete (including CVs, GCPs, Delegation and Training Logs).
- Nuclear Medicine close-out – Similar to a Pharmacy Close-out, the Nuclear Medicine manual and associated documents will be required to be up to date and complete.

Thank you to all site staff, past and present, for your contributions to the TheraP study!

Annual Closure Period

The ANZUP office will close from **Wednesday 22 December 2021** and will re-open on **Monday 10 January 2022**.

The NHMRC Clinical Trials Centre (CTC) will officially close from **Thursday 23 December 2021 at 5:00 PM AEDT** and will **re-open Monday 10 January 2022 at 9:00 AM AEDT**. NHMRC CTC phones/mailboxes will not be attended, however emergency cover will be provided.

Urgent Clinical Queries

If you have an urgent clinical query, **please email the query to ctc.sae@sydney.edu.au and also call +61 406 384 367 to confirm your query has been received**. Your query will be addressed as soon as possible by clinicians on call, however, please be aware that a response may take longer than usual.

General support

Please ensure any general enquiries requiring a prompt response are forwarded to the usual trial mailbox address by midday Thursday 23 December 2021. During the closure period, any enquiries of an urgent nature should be discussed with on-call staff by ringing **+61 406 384 367**.

Thanks again to everyone for your ongoing support for the TheraP trial. Wishing you all a happy holiday season. As always, please don't hesitate to get in touch at trials@anzup.org.au or therap.study@sydney.edu.au.



HAVE A HAPPY AND SAFE HOLIDAY SEASON

The ANZUP office will close COB 22 December 2021 and will reopen on 10 January 2022

TheraP key contacts

- Clinical trial operations, CTC E: therap.study@sydney.edu.au
- Coordinating PI: Michael Hofman E: michael.hofman@petermac.org
- Sponsor queries (payments, contracts) E: trials@anzup.org.au
- Trial pages: <https://anzup.org.au/clinical-trial/therap-trial/>