

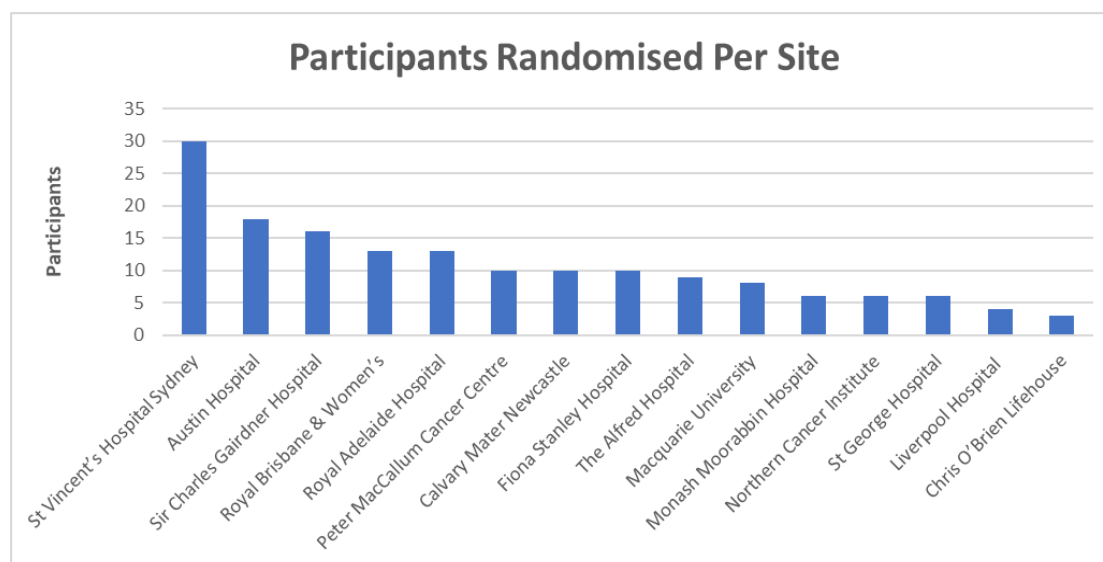
# ENZA-p Trial News

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

## Recruitment is now closed – CONGRATULATIONS!

A huge Thank You and Congratulations to everyone for your incredible contribution in reaching 162 eligible patients enrolled on ENZA-p! The final patient was randomised at Calvary Mater Hospital on Tuesday 26 July 2022.

Special congratulations to the teams at St. Vincent's Hospital who finished as our lead recruiter with 30 patients randomised, followed by Austin Hospital with 18 patients and Sir Charles Gairdner with 16.



*"An enormous thanks to the trial teams across Australia who have helped make this trial run so smoothly in conjunction with ANZUP and CTC. Despite COVID and a myriad of other setbacks, we have finished recruitment on track - now we just need to see whether combination treatment is worth it! Incredible work everyone. Thank you."*

**Study Chair: Professor Louise Emmett**



## No further progression timepoint circulating tumour cell collection

A quick reminder that going forward, the Streck tube blood collections are only required at baseline and day 92. Please do not collect or ship any further circulating tumour cell samples at the progression timepoint.

Normal TR blood collections in purple top vacutainers should continue at all three timepoints.

## Fresh tissue biopsies

Participating sites, please continue to look out for opportunities to take optional fresh tissue biopsies. Even if a baseline fresh tissue biopsy was not taken, a fresh tissue sample from time of progression is still useful as it is matched to PSMA/FDG PET scans also completed at this time.

## Patient Privacy Reminder

A reminder to all sites to ensure that patient names and other identifying details are removed from email chains prior to including the ENZA-p mailbox. Similarly, any documents must be de-identified before sending to the CTC or any other external party. Providing any patient identifying details to these parties is considered a breach of GCP and a Corrective and Preventative Action (CAPA) plan is required for every occurrence on trial.

## Follow-up visits

A quick reminder on ENZA-p follow-up visit schedules for patients ending study treatment:

- **At end of treatment:** Conduct visits at 42 days and 84 days after last dose of study treatment, including assessment of AEs.
- **Prior to radiological progression:** Continue full follow-up visits 6-weekly and ongoing CT/WBBS imaging 12-weekly.
- **After radiological progression:** Continue limited follow-up visits 12-weekly (for survival and subsequent treatment data only).

Please refer to the schedule of assessments in the ENZA-p protocol for the list of assessments required at each visit. If you have any questions then please don't hesitate to contact the team at [enza-p.study@sydney.edu.au](mailto:enza-p.study@sydney.edu.au).

## In collaboration with:



Australian Government  
Cancer Australia



## Translational Research

Please continue to collect Translational Research (TR) bloods from all participants at:

- Baseline (after randomisation)
- Day 92
- At disease progression (PSA or radiological; prior to starting subsequent therapy)\*

**\*At progression timepoint DO NOT COLLECT Streck tube circulating tumour cell samples.**



**Enter** all TR blood collections into **Medidata** using 'TR Blood' log lines within the 'TR' folder.

For the circulating tumour cell collections (**now taken at baseline and Day 92 only**) shipping to Singapore **email** the completed blood collection form **in real time** to [enza-p.study@sydney.edu.au](mailto:enza-p.study@sydney.edu.au) and [CTXLPSSING@covance.com](mailto:CTXLPSSING@covance.com). Any forms previously not sent should be emailed now as the ENZA-p team will be reaching out for any outstanding blood collection forms shortly.

- **TIP:** If a TR blood timepoint is missed (and will never be collected), go to the blood form in Medidata, answer "Was blood for translational research collected at this visit?" as 'No' and provide the reason.

## 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.

Please send through **DE-IDENTIFIED** copies of CT/WBBS 12 weekly scans for all study participants to the [enza-p.study@sydney.edu.au](mailto:enza-p.study@sydney.edu.au) mailbox, and ensure that the following scans are also uploaded to WIDEN:

- CT/WBBS (screening, D99, 12-weekly, progression)
- PSMA PETs (screening, D92, progression)
- FDG PETs (screening, progression)
- SPECT/CTs (Lu-PSMA cycles 1-4)

***Thanks again to everyone for your ongoing support for the ENZA-p trial.  
As always, please don't hesitate to get in touch at [enza-p.study@sydney.edu.au](mailto:enza-p.study@sydney.edu.au).***

## ENZA-p key contacts

- Clinical trial operations, CTC E: [enza-p.study@sydney.edu.au](mailto:enza-p.study@sydney.edu.au)
- Coordinating PI: Louise Emmett E: [louise.emmett@svha.org.au](mailto:louise.emmett@svha.org.au)
- Sponsor queries (payments, contracts) E: [trials@anzup.org.au](mailto:trials@anzup.org.au)
- Trial information: <https://anzup.org.au/clinical-trial/enza-p/>

### UPCOMING MEETINGS:

Wednesday 3 August 2022

TMC: 3pm – 4pm

TR: 4pm – 4:30pm