

ENZA-p Trial News

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Welcome to the September 2021 edition of the ENZA-p newsletter

****WE'VE REACHED 50% RECRUITMENT!****

A huge Thank You and Congratulations to all our wonderful ENZA-p site teams for your contribution to the trial recently reaching 50% recruitment!

There are currently 84 of 160 patients randomised, with our top recruiters including St Vincent's with 20 patients randomised, Austin with 12 patients randomised, closely followed by Royal Brisbane & Women's Hospital with 11 patients randomised.

A special mention also to the teams at The Alfred Hospital and Sir Charles Gairdner, both ramping up recruitment and randomising a combined 9 new patients in the past two months.

Site accrual

Site	PI	Patients randomised
St Vincent's Hospital Sydney	Anthony Joshua	20
Austin Hospital	Andrew Weickhardt	12
Royal Brisbane & Women's	Jeffrey Goh	11
Sir Charles Gairdner	Siobhan Ng	7
The Alfred Hospital	Mark Voskoboynik	7
Peter MacCallum	Shahneen Sandhu	6
Calvary Mater Newcastle	Craig Gedy	6
Royal Adelaide Hospital	Hsiang Tan	6
Fiona Stanley Hospital	Andrew Redfern	5
Liverpool Hospital	Wei Chua	2
Northern Cancer Institute	Laurence Krieger	1
Chris O'Brien Lifehouse	Lisa Horvath	1
Monash Health	David Pook	0
TOTAL		84

Study Chair: Professor Louise Emmett



SAE reporting for every hospitalisation

A reminder that SAEs must be reported until 12 weeks after last dose of Lu-PSMA or 30 days after last dose of enzalutamide, whichever is later.

The ENZA-p protocol does not list SAE reporting exemptions (e.g. for elective admissions or admissions related to prostate cancer), so **every hospitalisation** occurring within the reporting period must be reported as an SAE.

'First progression' assessments

Please keep in mind when reviewing patients that there are a number of assessments required at the time of first progression – PSA progression or radiological progression, whichever occurs first.

'First progression' assessments include:

- Clinic visit (biochemistry & haematology bloods, PSA, AEs, QOLs)
- FDG PET scan
- PSMA PET scan
- CT and bone scan
- TR blood sample

For most patients, PSA progression occurs first so please keep a close eye on the PSA values. For guidance on PSA progression occurring in the first 12 weeks of treatment, or progression occurring shortly after day 92 PSMA PET scans, please contact the CTC.

WIDEN uploads and scan reports

Please continue to upload all trial imaging to WIDEN as the scans are completed:

- PSMA PET scans (screening, D92, PD)
- FDG PET scans (screening, PD)
- SPECT/CT scans (24hrs post Lu-PSMA) + corresponding Time & Motion data (once per pt)
- CT scans (baseline, D99, 12-weekly) + send de-identified scan report to ENZA-p team
- Whole body bone scans (baseline, D99, 12-weekly) + send de-identified scan report to ENZA-p team

As always, please don't hesitate to contact the ENZA-p CTC team at enza-p.study@sydney.edu.au should you have any questions regarding the trial.

In collaboration with:



Translational Research

Blood for translational research.

- Collect, process and store the standard ENZA-p serial bloods (3 timepoints) at baseline, Day 92 and first progression (PSA or radiological) from all patients
- Also recover peripheral blood mononuclear cells (PBMCs) (at selected sites)
- Courier bloods to (Epic Sciences, Singapore) in real-time for the circulating tumour cells study
- Enter the blood collection details in Medidata



Tissue for translational research.

- Biopsies (processed and cryopreserved at site) at baseline and progression are collected at selected participating sites only and optional for patients
- Archival tissue (all patients) – when requested by the coordinating centre

#ANZUP21 - SUNDAY 17 & MONDAY 18 October 2021
REGISTER TODAY!



#ANZUP21 is the one event you don't want to miss this year, so put the date in your diary and [register](#) today!

We have a stellar line up of national and international speakers - view the [program here](#).

ENZA-p key contacts

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- Coordinating PI: Louise Emmett E: louise.emmett@svha.org.au
- Sponsor queries (payments, contracts) E: trials@anzup.org.au
- Trial information: <https://anzup.org.au/clinical-trial/enza-p/>