

EVOLUTION Trial News

www.anzup.org.au

Welcome to the first EVOLUTION newsletter for 2023!

As of the end of January, we have randomised over 50% of our target number of patients for this study! We are so grateful for everyone's support on this exciting research. Since our last newsletter, we have progressed to having 7 of our 9 sites open to recruitment, with our last two sites anticipated to open in February 2023.

Site	PI	Activation date	Patients randomised
Peter MacCallum Cancer Centre	Shahneen Sandhu	04 May 2022	10
Austin Hospital	Andrew Weickhardt	13 Jul 2022	11
Royal Adelaide Hospital	Hsiang Tan	04 Jul 2022	12
Royal Brisbane Hospital	Jeffrey Goh	08 Sep 2022	11
Calvary Mater Hospital	Craig Gedye	15 Aug 2022	8
St Vincent's Hospital	Anthony Joshua	18 Sep 2022	6
Alfred Hospital	Mark Voskoboynik	24 Nov 2022	2
St George Hospital	Patricia Bastick	14 Feb 2023	0
Sir Charles Gairdner Hospital	Siobhan Ng	N/A	N/A

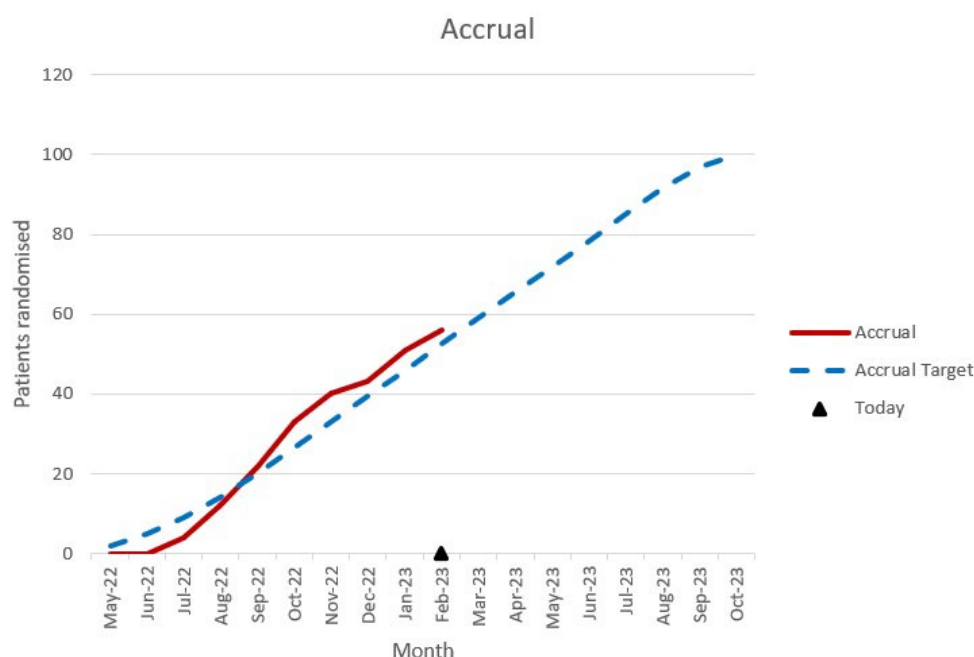
Study Co-Chairs



A/P Shahneen Sandhu



Prof Louise Emmett

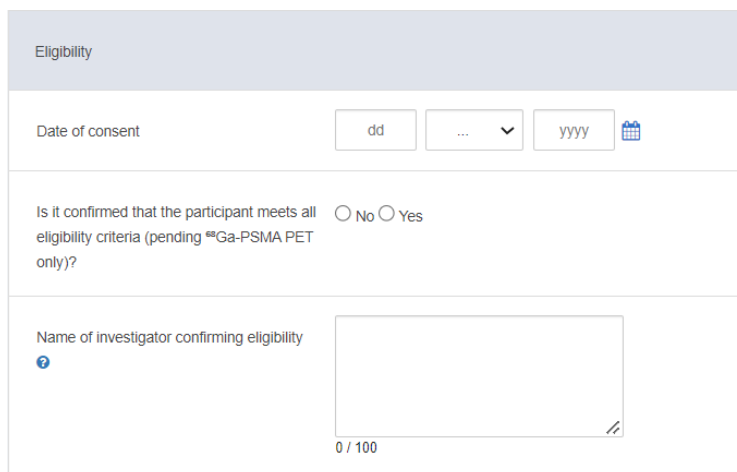


Upcoming TMC – Wednesday 1 March at 3.30pm AEDT

Please be reminded that the Evolution Study TMC will be taking place on Wednesday 1 March. If any Principal Investigators have not received an invitation then please contact the ANZUP team at trials@anzup.org.au.

Helpful hint - Patient not appearing in WIDEN?

If you find that you have registered a patient but are not able to see them in WIDEN, check that you have completed the ENROL form in Medidata (see below). Once the fields below have been completed, the patient will appear in WIDEN. If the patient is still not appearing, then please contact the EVOLUTION study team at evolution.study@sydney.edu.au.



The screenshot shows a form titled "Eligibility" with the following fields:

- Date of consent: A date picker with "dd", "...", "yyyy", and a calendar icon.
- Is it confirmed that the participant meets all eligibility criteria (pending ⁶⁸Ga-PSMA PET only)?: Radio buttons for "No" and "Yes".
- Name of investigator confirming eligibility: A text input field with a character count "0 / 100" and a small blue icon.

ANSTO shutdown period

Please be reminded that ANSTO has a number of shutdown periods coming up in March/April. ITM will be supplying Lutetium in the periods where the ANSTO reactors are shut down; as a result, some orders for Lutetium may be required earlier than usual to ensure they meet the cut-off. The latest ANSTO Order Cut off Times sheet was updated 13 Feb 2023 and has been circulated to all sites. Please contact the Evolution study mailbox at evolution.study@sydney.edu.au if you have not received this document.

DHL invoices

Please be reminded that customs invoices for DHL from PSMA shipments should be forwarded with immediacy to the Evolution study team inbox at evolution.study@sydney.edu.au. Please also forward any correspondence from DHL staff regarding held shipments to the Evolution study team in case follow up is required.

In collaboration with:



Medidata eCRF hints and tips

Visit	Folders and forms to complete in EDC	Timing/additional information
Screening	SCREENING folder: <ul style="list-style-type: none"> Screening Log form 	Required for all screened patients.
(Following confirmation of eligibility)	ENROL folder: <ul style="list-style-type: none"> Enrol form Rand form Consent folder: <ul style="list-style-type: none"> log line for initial consent 	<p>Expected randomisation date is within 28 days from screening.</p> <p>Consent form is triggered at the bottom of the left-hand side menu.</p>
BASELINE	BASELINE folder: <ul style="list-style-type: none"> All forms triggered in folder IMAGING folder: <ul style="list-style-type: none"> Lesion Y/N form TA date (2x log lines – CT & WBBS) SOFT TISSUE lesions form BONE baseline form PSA folder: log line for Baseline PSA TR folder: <ul style="list-style-type: none"> log line for baseline TR blood log line for baseline TR tissue, if collected 	<p>Baseline visit expected date is within 7 days prior to cycle 1 day 1.</p> <p>If Baseline visit is on the same day as C1D1, please complete the BASELINE folder and the VISIT 1 folder.</p>
Study treatment Weeks 1-25	<p>At every visit:</p> VISIT folder: <ul style="list-style-type: none"> Date Med Onc Assessment form QOL Completion (if triggered) Study Treatment folder: <ul style="list-style-type: none"> log lines for visit treatment PSA folder: <ul style="list-style-type: none"> log line for PSA result AE folder: <ul style="list-style-type: none"> AE form Hospitalisation and Con Med forms to be completed following an SAE <p>At applicable timepoints:</p> IMAGING folder: <ul style="list-style-type: none"> TA date (2x log lines – CT & WBBS) SOFT TISSUE lesions form BONE form TR folder: <ul style="list-style-type: none"> log line for TR blood log line for TR tissue, if collected 	<p>Study treatment is due to start within 21 days following randomisation.</p> <p>If Baseline visit is at the same time as C1D1, please complete the BASELINE folder and the VISIT 1 folder with the same date.</p> <p>Study treatment start date (first log line on the Study treatment folder) should be the same as VISIT 1 date.</p> <p>Visit dates are expected every 3 weeks \pm7 days until Week 25 or radiological progression.</p>

EVOLUTION key contacts

- Clinical trial operations, CTC E: evolution.study@sydney.edu.au
- Coordinating PI: Shahneen Sandhu E: shahneen.sandhu@petermac.org
- Sponsor queries (payments, contracts) E: trials@anzup.org.au
- Trial information: <https://anzup.org.au/clinical-trial/evolution/>