

# DIPPER Trial News

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## Welcome to the first DIPPER newsletter

DIPPER activated its first site, St Vincent's Hospital Sydney, on 11 May 2023, followed by Royal North Shore Hospital and Royal Brisbane & Women's Hospital on the 26 May 2023 and Redcliffe Hospital on the 2 June 2023. Peter MacCallum Cancer Centre is working towards obtaining regulatory approval and site activation and is expected to open within the next 1-2 months. A special thank you and congratulations to all involved for your contribution and commitment to reach this milestone!

### Study Chair: Associate Professor Matthew Roberts



*"This trial has been the culmination of more than 3 years of planning by a national, multidisciplinary steering committee, with key consumer and supportive care input, as well as many clinician opinions (via survey)."*

*We are grateful for the support of clinicians and patients in recruiting to this trial to shed light on this important clinical question."*

## WHAT IS DIPPER?

The DIPPER trial will use modern clinical risk stratification and PSMA PET/CT imaging to investigate if surveillance of early biochemically recurrent prostate cancer and salvage radiation therapy are different, both for cancer outcomes (event-free survival), side-effect profile and patient reported outcomes. This clinical scenario is an unmet need for clinicians and patients, as we don't know if surveillance is oncologically safe, but we also don't know if salvage radiation therapy produces comparably worse side effects to justify the oncological benefits. The patient reported outcomes in this scenario are also key, as the attitudes and fears of these patients is largely unknown.

## Study team introduction

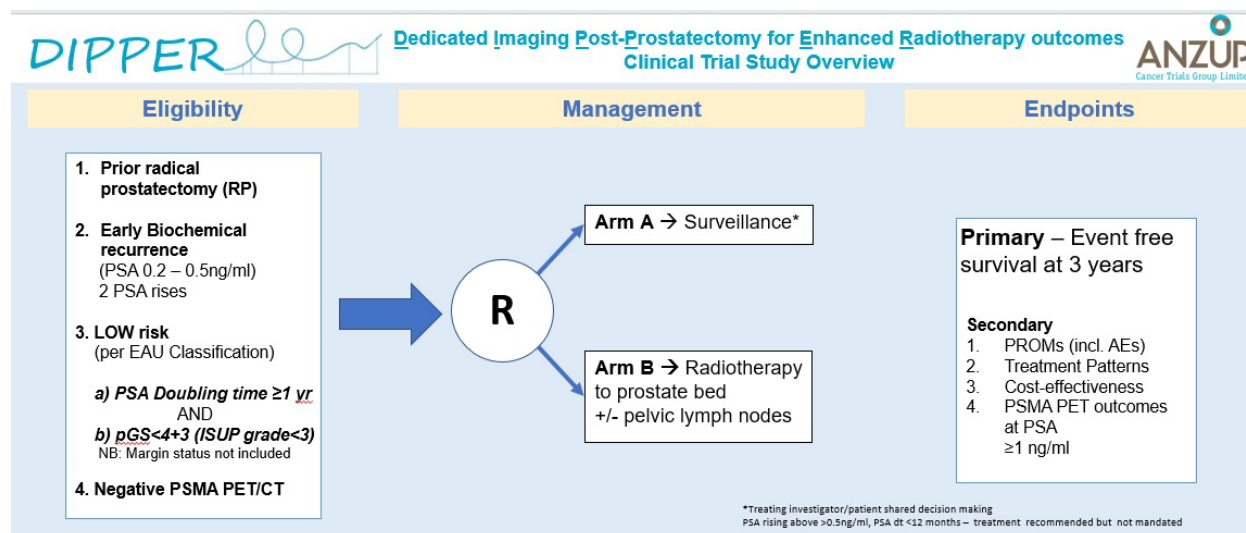
**Study Chair:** Associate Professor Matthew Roberts

**Deputy Chair:** Professor Louise Emmett

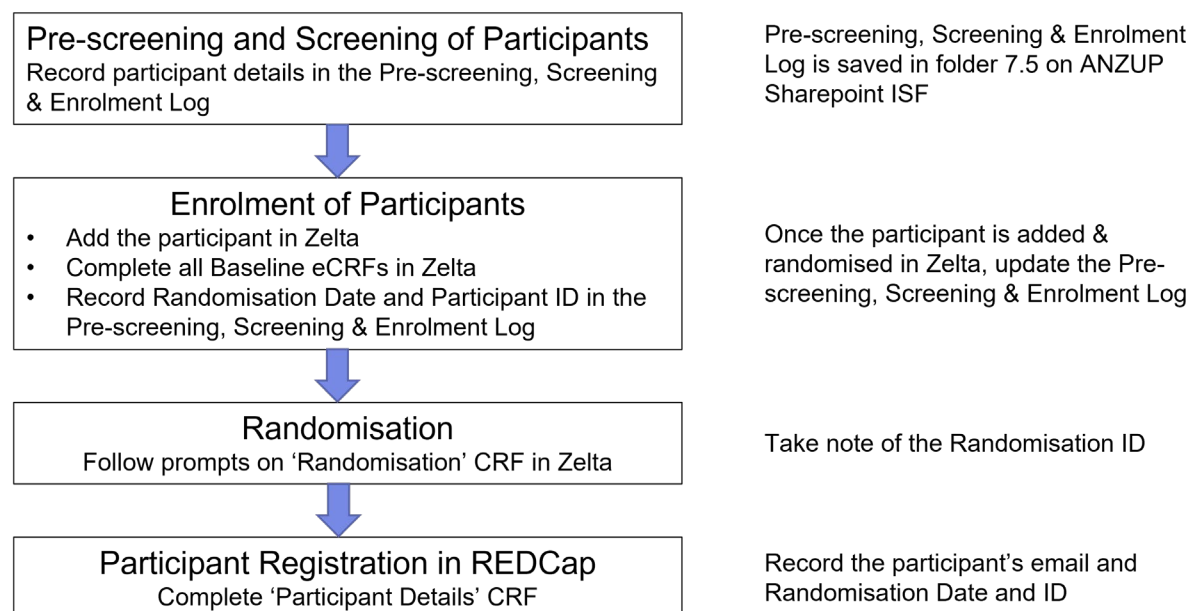
### Contact us:

**Email:** [dipper@georgeinstitute.org.au](mailto:dipper@georgeinstitute.org.au) which is the trial mailbox for all your study related questions or [trials@anzup.org.au](mailto:trials@anzup.org.au) for any sponsor related queries.

## Study Schema:



## DIPPER Patient Registration and Randomisation Process



## DIPPER Databases

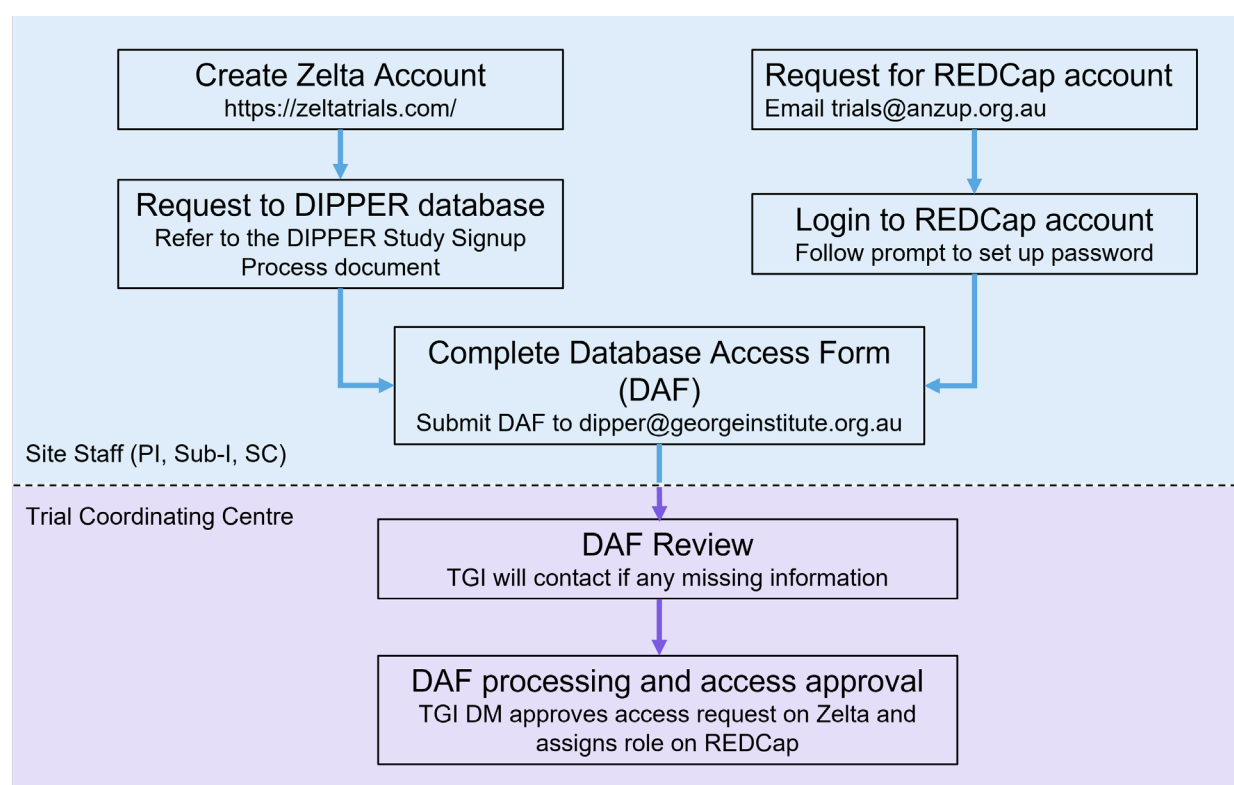
The DIPPER trial has two databases:

1. Zelta (formerly known as IBM Clinical) to randomise participants and record clinical data - <https://zeltatrials.com/>
2. REDCap to manage patient-reported health questionnaires - <https://redcap.anzup.org.au/>

## Reminders/Notifications

- Remember to register participant in REDCap once randomised in Zelta. For quick review, see Patient Registration and Randomisation Process diagram below.
- Please prompt participants for their email to be entered in REDCap. This ensures that they receive all QoL Questionnaires.
- For how to request access to study databases, please see the Request to Zelta & REDCap Database Process below.
- Centralised monitoring will commence when the first 2-3 participants are randomised. TGI Operations will first monitor that participant registration is done correctly in REDCap.

## Request to Zelta & REDCap Database Process



## DIPPER key contacts

The DIPPER trial is sponsored by ANZUP, with operational, statistical and data management services provided by The George Institute for Global Health.

Clinical trial operations queries (study related and monitoring), TGI E: [dipper@georgeinstitute.org.au](mailto:dipper@georgeinstitute.org.au)

Coordinating PI: **Matthew Roberts**

For all study related and monitoring queries: [dipper@georgeinstitute.org.au](mailto:dipper@georgeinstitute.org.au)

Sponsor related queries (payments, contacts) E: [trials@anzup.org.au](mailto:trials@anzup.org.au)

Trial information: <http://anzup.org.au/clinical-trial/dipper/>