ANZUP 1601

KEYPAD Trial News

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Welcome to the second KEYPAD newsletter

Since opening the first sites in December 2017, we are pleased to report that 12 KEYPAD sites are now activated across Australia. A further two sites are completing local approval processes with activation anticipated in the next couple of months. A huge thank you to all KEYPAD site staff for your ongoing hard work in getting this important study opened at your hospital.

Current recruitment

Site *(in order of activation date)*	Activation date	Patients
Calvary Mater Newcastle	11/12/2017	2
St George Hospital	11/12/2017	3
Eastern Health / Box Hill	11/12/2017	0
Royal Brisbane & Women's Hospital	22/12/2017	0
Northern Cancer Institute	22/12/2017	0
Concord Repatriation General Hospital	24/01/2018	1
Flinders Medical Centre	16/02/2018	0
Icon Cancer Care	11/04/2018	1
Peter MacCallum Cancer Centre	28/03/2018	1
Monash Health	23/05/2018	0
Ballarat Oncology	20/06/2018	1
Fiona Stanley Hospital	18/07/2018	0
Sunshine Coast University Hospital	Expected Q3 2018	-
Macquarie Hospital	Expected Q3 2018	-
Total	**14**	**9**

KEYPAD recently experienced a small surge in recruitment with 3 new patients enrolled in July. This brings total accrual to 9 patients. Please contact keypad@ctc.usyd.edu.au if you have any eligibility queries.

KEYPAD is a collaboration between ANZUP and NHMRC Clinical Trials Centre.

This investigator initiated ANZUP study has been supported both financially and with study drug by MSD and Amgen.
ANZUP is supported by the Australian Government through Cancer Australia.

ANZUP Annual Scientific Meeting (ASM)

ANZUP's recent ASM was a great opportunity to meet some of KEYPAD's site staff and hold the first face-to-face Trial Management Committee (TMC) meeting. Discussions highlighted the importance of this study and the various recruitment strategies to ensure KEYPAD's profile is maintained within each site.

The following recommendations were made:

- Communication is key to keeping KEYPAD on the agenda at every site. It is imperative all oncologists on-site are aware of the study, and KEYPAD participation is considered as an option for any patient progressing during or after treatment with a VEGFR TKI and prior to starting other treatments.
- Promote KEYPAD at MDT meetings and include study information in any internal trial updates or newsletters. Study slides are available from CTC if required.

ASM continued

- Principal Investigators are encouraged to utilise their referral networks to seek potential patients for the study. If you have any useful strategies or comments on cross-referral that have worked at your site, we would love to hear them.
- Please share CTC's trial update emails and ANZUP's newsletters with colleagues in and outside your site.
- ANZCTR, Clinical Trials.gov and the ANZUP ClinTrial Refer app are excellent tools for study reference including KEYPAD hospitals and contact numbers.
- Flag patients currently on VEGFR TKI treatment on your hospital's EMR. If/when disease progression occurs, the patient's treating oncologist will be aware that KEYPAD may be a potential treatment option.

Data management

Recording Adverse Events (AEs)

The date of AE assessment should correspond with the SUBSEQUENT visit date (i.e. assessed next time the participant attends the clinic). See example.

TREAT visit 1 – 01 Jan 2018	- Assessment and cycle 1 treatment details ➢ **AE form dated 22 Jan 2018** (completed at next visit)
TREAT visit 2 – 22 Jan 2018	- Assessment and cycle 2 treatment details ➢ **AE form dated 12 Feb 2018** (completed at next visit)
TREAT visit 3 – 12 Feb 2018	- Assessment and cycle 3 treatment details ➢ **AE form dated 05 Mar 2018** (completed at next visit)
TREAT visit 4 – 05 Mar 2018	- Assessment and cycle 4 treatment details ➢ **AE form dated 26 Mar 2018** (completed at next visit)

CT scan schedule

- Please follow the CT scan schedule outlined in the protocol schedule of assessments (section 6.1), i.e. weeks 12, 18, 24 then every 12 weeks until PD.
  eCRF helptext error: Note that the DATE form within the TA visit provides an incorrect schedule for these assessments. Please ignore this incorrect help text and follow the schedule above, per the protocol.
- Please note a CT brain scan should be performed at baseline, and only needs to be repeated if abnormal or as clinically indicated.

AUTO-CHECK Study

- REMINDER: remain vigilant for IRAEs throughout follow up – including beyond the 100-day safety reporting period.
- Collect AUTO-CHECK bloods whenever a significant IRAE occurs (ideally before starting steroids) or at the next clinic visit.

Update (as at 1 August 2018)

- Trials/cohorts activated **6/7**
- Hospital sites activated **54** (unique sites: 35)
- Patients participating **120** (40% of the target 300)
- Real-time blood shipments (to Canberra) **187**
- IRAE blood samples collected **16** (13% of patients).

Protocol amendment

Protocol amendment (**V3.0, 17 April 2018**) was submitted and approved by lead HREC on 4 May 2018. Thanks to all site staff who promptly actioned review and submission to their RGO. Please ensure a copy of the acknowledgement is forwarded to CTC once available.

KEYPAD key contacts

- **Clinical trial operations, CTC E:** keypad@ctc.usyd.edu.au **and** kate.ford@ctc.usyd.edu.au
- **Sponsor queries (e.g. site payments, contracts) E:** simran.chawla@anzup.org.au **T: +61 2 8036 5271**
- **Coordinating PI: Craig Gedye E:** craig.gedye@newcastle.edu.au
- **Trial pages:** https://www.ctc.usyd.edu.au/our-research/clinical-trials/trial-pages-login.aspx (log in required) here you will find downloadable copies of all study documents and tools.
- **ANZUP ClinTrial Refer app available for download from iTunes and Google Play**