

Phase 3 BEP Study News

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Welcome to the December 2023 Phase 3 BEP newsletter

Greetings from the P3BEP team! We have now recruited 289 patients as of 4 December 2023. Thank you to all our Site Investigators trial staff and international coordinating centres for your continued collective efforts to contribute to the P3BEP study. Please keep up the great work!

Wishing you all a happy holiday season. As always, please don't hesitate to get in touch at trials@anzup.org.au or p3bep.study@sydney.edu.au.

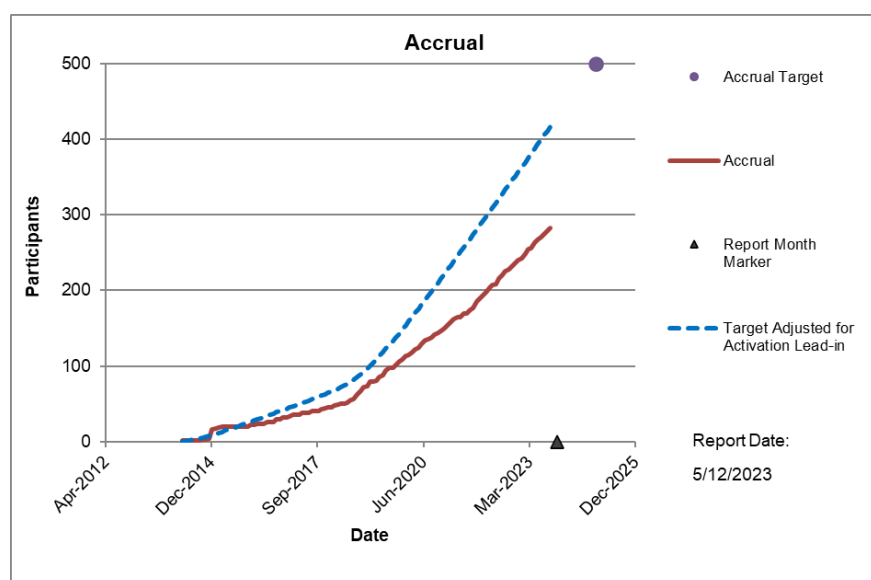
Overall accrual

Study Accrual

Target Recruitment: 500

No. of patients randomised: 289

Overview of Study Accrual and International Collaborations



Study Overview

The current gold standard practice for the treatment of germ cell tumours is the use of a chemotherapy combination called BEP which consists of three chemotherapy agents, Bleomycin, Etoposide and Cisplatin administered on a 3-weekly cycle.

BEP is given with a drug called pegylated G-CSF (or pegfilgrastim) which stimulates white blood cell production. The purpose of this study is to determine whether giving the same dose of BEP on a 2-weekly schedule will be more effective than a 3-weekly schedule and will be well tolerated. The 2-weekly schedule is called 'accelerated BEP'.



PHASE 3 BEP STUDY CHAIR
A/Professor
Peter Grimison

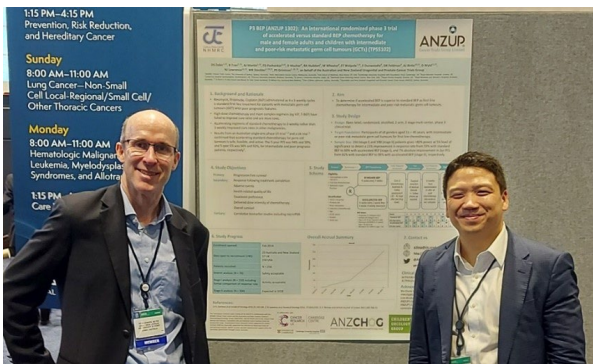
Overview of Study Accrual and International Collaborations, cont.....

Study Recruitment Status		
Region	Lead Group	# Participants Randomised
Australia / New Zealand	ANZUP	105 (AU: 90, NZ: 15)
US / Canada	Children’s Oncology Group	109
UK	Cambridge Clinical Trials Centre - Cancer Research UK	75
Total		289

[Click here to view the full recruitment tables.](#)

P3BEP presentations

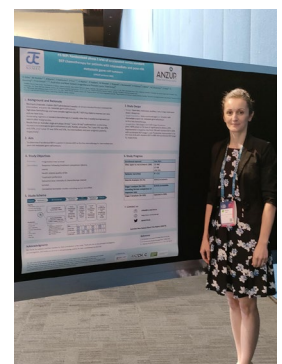
Thank you to Danka, our P3BEP research fellow, who presented the P3BEP study at ASCO GU 2023 in February, and our study chair Peter Grimison and co-study chair Ben Tran who presented at ASCO 2023 in June.



Left, Peter Grimison (ANZ P3BEP study chair);
Right, Ben Tran (Co-Study Chair)



Left, Peter Grimison (ANZ P3BEP study chair);
Middle, Chris Sweeney (Uni of Adelaide);
Right, Lindsay Frazier (Children's Oncology Group Lead, Dana Farber)



Danka Zebic (Fellow)

NHMRC Clinical Trials and Cohort Studies (CTCS) and Cancer Australia Grant 2023

We are pleased to inform you that we submitted the NHMRC CTCS and Cancer Australia Grant in August 2023. Thank you to all those who contributed including our CAP members. The result of this application should be available in April 2024.

ANZUP’s new offices

Please note that the ANZUP office is relocating on the 11 December 2023 and our new address is: Level 18, Tower 3, 300 Barangaroo Avenue, Barangaroo NSW 2000.

Data Entry Reminders – InForm eCRF

InForm eCRF	Action Required
SAE reporting	Please remember to enter all SAEs into InForm within 1 working day of the investigator becoming aware of the event. Please refer to the current P3BEP eCRF completion guidelines V5.0 dated 07-Dec-2021.
Translational Research	A reminder to please complete the TR Blood Form (refer to instructions on pg. 16 of eCRF guidelines).
General data entry	Please ensure all data entry is up to date in InForm, eCRFs are to be completed within 2 weeks of the date of visit.

Additional Blood Collections for Translational Research

Please be reminded that if a patient consents to the additional collections, samples should be collected on study **D1, D15, and D22 prior to treatment**. Please record details on the collection forms (Appendix A of the Biospecimen Collection Manual v3.0) and **scan through a copy of the completed forms to p3bep.study@sydney.edu.au after each collection**. Please reach out to your country specific coordinating centre for additional details.

We are grateful to Cancer Australia for their financial support to conduct the study. Phase 3 BEP Study is being led by ANZUP Cancer Trials Group in collaboration with the NHMRC CTC, Children’s Oncology Group (USA) and Cambridge University Hospitals NHS Foundation Trust (UK).



Australian Government
Cancer Australia



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Phase 3 BEP key contacts

- Clinical trial operations E: p3bep.study@sydney.edu.au T: +61 2 9562 5000
- Sponsor queries (e.g. site payments, contracts) E: trials@anzup.org.au
- Coordinating PI: A/Prof Peter Grimison E: peter.grimison@lh.org.au
- Trial information: <https://anzup.org.au/clinical-trial/p3bep/>