

Phase 3 BEP Study News

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Welcome to the April 2025 Phase 3 BEP newsletter

Greetings from the P3BEP study team! We are excited to share that we have now successfully enrolled 355 patients, reflecting an increase of 36 patients since our last update in September 2024. A sincere thank you to all our site teams and international coordinating centres for your ongoing dedication and hard work on the P3BEP study. Keep up the excellent work!

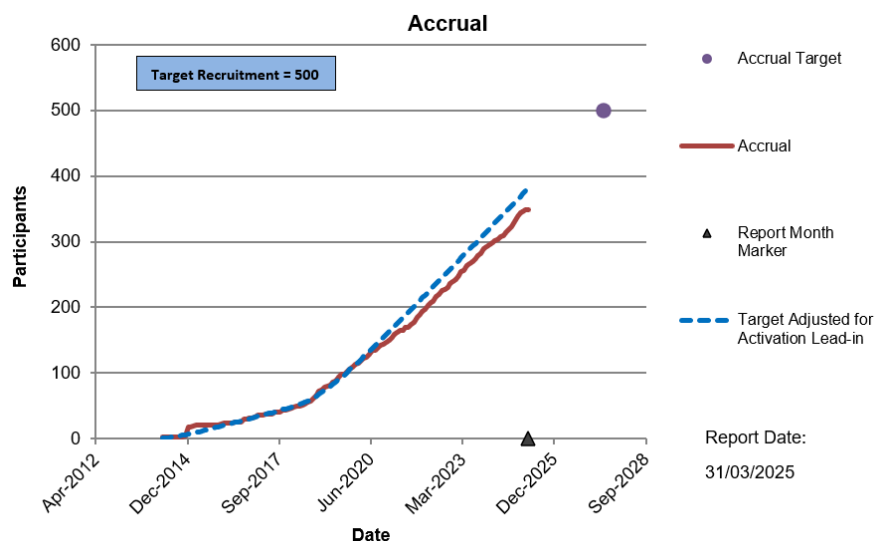
We are also pleased to introduce Shiou Tan (*pictured*) as the new Project Manager for the P3BEP study. A special thank you to Alik Rasmiena for her incredible hard work and positive impact on the study. We wish her all the best as she begins her maternity leave.



We are excited to welcome Dr Brandon Lau from Perth, WA, to the TMC team. Currently, we are working on activating their site at Sir Charles Gairdner Hospital in the ANZ region. We look forward to the contributions Brandon and the team at Sir Charles Gairdner Hospital will bring as we continue to expand our network.

A/Professor Peter Grimison & the P3BEP Team

Overview of Study Accrual and International Collaborations



Overall accrual

Study Accrual

Target Recruitment: 500

No. of patients randomised: 355 (*as at 31 March 2025*)



PHASE 3 BEP STUDY CHAIR
A/Professor
Peter Grimison

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

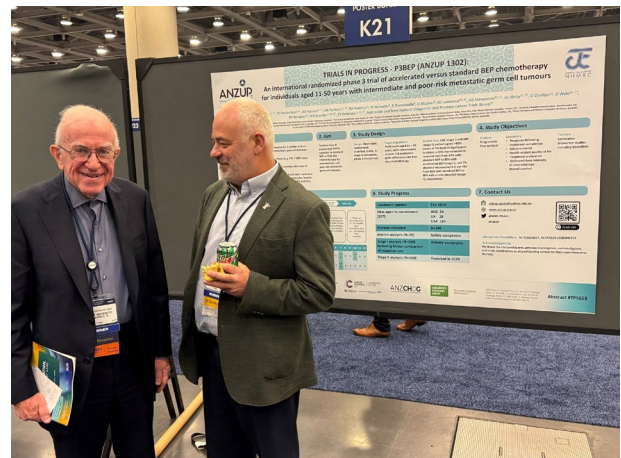
Study Recruitment Status		
Region	Lead Group	# Participants Randomised
Australia / New Zealand	ANZUP	115 (AU: 100, NZ: 15)
US / Canada	Children's Oncology Group	150
UK	Cambridge Clinical Trials Centre - Cancer Research UK	90
Total		355

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

P3BEP presentations

Thank you to Martin Stockler from the NHMRC Clinical Trials Centre, who presented the P3BEP study at ASCO GU in February 2025 on behalf of the study team (*pictured with Cancer Research pioneer Larry Einhorn*).

TRIALS IN PROGRESS –P3BEP (ANZUP 1302): An international randomized phase 3 trial of accelerated versus standard BEP chemotherapy for individuals aged 11-50 years with intermediate and poor-risk metastatic germ cell tumours



Successful transition from InForm database to REDCap platform

We're happy to announce that the transition from the InForm database to the REDCap database, which took place in December 2024, was a success with REDCap now fully operational. We would like to thank everyone for their cooperation and dedication throughout this process, and we look forward to continuing our work with this new platform.

For staff members who are yet to complete their REDCap training to obtain user access, the REDCap training instructions can be accessed via: <https://redcap.sydney.edu.au/surveys/?s=AY4LHHXFE4TRDKWD>.

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 (ANZUP 1302)



Quality of Life (QoL) booklet completion – ANZ/UK sites only

Please ensure that you are using the **QoL Questionnaire Booklet v1.1 (Feb 2014)** rather than the appendices from the protocol. Please complete each page and enter the **Study/Participant No.** and **Visit No.** (as shown in the screenshot) on each page. This will help us accurately capture the Participant No. and specific timepoint when the questionnaire was completed.

Additionally, when submitting copies of this source documentation to the CTC, please ensure that all **6 pages** are included, as requested.

Phase 3 BEP Trial (ANZUP1302)

Study No.

 /

Example:

Study No. 21 = 021

Visit No.

001 - Before Cycle 1
002 - Before Cycle 2
003 - Before Cycle 3
004 - Before Cycle 4
005 - Before Additional Bleomycin cycle (Arm B)
030 - 30 day safety assessment
100 - Final response assessment
201 - FUP 9 months after randomisation
202 - FUP 12 months after randomisation
203 - FUP 18 months after randomisation

Additional Blood Collections for Translational Research

Please be reminded that if a patient consents to the additional collections, samples should be collected according to your country-specific schedule of assessments in the protocol. Please reach out to your country specific coordinating centre for additional details.

We are grateful to the NHMRC 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).



**CHILDREN'S
ONCOLOGY
GROUP**

The world's childhood
cancer experts



**ANZUP ANNUAL
SCIENTIFIC MEETING**
'LISTEN, REFLECT, CONNECT'

ANZUP's Annual Scientific Meeting
20-22 July 2025, Hyatt Regency Sydney

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 T: +61 2 9562 5000
- Coordinating PI: A/Prof Peter Grimison E: peter.grimison@lh.org.au
- Trial information: <https://anzup.org.au/clinical-trial/p3bep/>