ANZUP Cancer Trials Group Limited

Phase 3 BEP Study News

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Welcome to the July 2021 Phase 3 BEP newsletter

Greetings from the P3BEP team! We hope everyone is keeping safe and well as we head into the second half of 2021. Thank you to all of our site teams for your ongoing participation and effort screening and recruiting patients to P3BEP this year. We have now recruited 166 patients, including 22 patients enrolled since the last update at the end of 2020.

Study accrual and international collaborations

Study Accrual
Target Recruitment: 500
No. of patients randomised: 166

Australia and New Zealand Accrual

Site Name	Activation Date	Participants
Peter MacCallum Cancer Center	15/05/2014	12
Chris O'Brien Lifehouse	28/11/2014	10
Princess Alexandra Hospital	16/06/2014	7
Nepean Hospital	10/03/2014	6
Royal Brisbane and Women's Hospital	08/04/2014	6
Auckland Hospital	12/12/2014	5
Prince of Wales Hospital	19/02/2014	4
Fiona Stanley Hospital	19/03/2014	4
Royal Adelaide Hospital	1/07/2014	3
Border Medical Oncology	20/07/2015	3
Austin Health	11/06/2014	2
Calvary Mater Newcastle	04/03/2014	2
Box Hill Hospital	19/06/2014	2
Christchurch Hospital	26/11/2014	2
Starship Children's Hospital	18/09/2018	2
Royal Hobart Hospital	16/06/2014	1
Concord Repatriation General Hospital	14/03/2014	1
Macquarie Cancer Clinical Trials	21/08/2014	1
Palmerston North Hospital	12/12/2014	1
Flinders Medical Centre	07/04/2015	1
Queensland Children's Hospital	03/04/2019	1
Christchurch Children's Haematology Hospital	02/04/2019	1
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PHASE 3 BEP STUDY CHAIR

A/Professor Peter Grimison

Interim Analysis and Data Entry Reminders

As you will recall, we are preparing for an interim analysis of response data for the first 150 patients on study. We recruited our 150th patient in January 2021, and we expect response data for this patient to be available by early August. As this date quickly approaches, **please ensure all data entry is up to date in InForm, particularly the response data for the End of BEP Treatment and Final Response visits.** Please also ensure any outstanding queries have been resolved. Our data management team will be sending out Overdue Form and Open Query Requests more frequently over the next couple of months. Please reach out if you have any questions: p3bep.study@sydney.edu.au

International Accrual

COG - USA		
Site Name	Activation Date	Participants
Lucile Packard Children's Hospital Stanford	04/12/2018	5
Washington University Medical Center	13/08/2018	3
Rady Children's Hospital	05/09/2018	2
Geisinger Medical Center	24/04/2019	2
University of Texas Health Science Center at San Antonio	28/02/2020	2
Carolinas Medical Centre	13/05/2019	2
Memorial Sloan Kettering Cancer Centre	26/03/2020	2
University of Mississippi Medical Centre	30/10/2018	1
University of Wisconsin Hospital	11/06/2019	1
Memorial Health University Medical Center	18/12/2018	1
Vanderbilt University Medical Centre	08/11/2018	1
Augusta University Medical Centre	12/10/2018	1
Miller Children's and Women's Hospital Long Beach	01/08/2019	1
Palmetto Health Richland	26/04/2019	1
Methodist Children's Hospital of South Texas	27/05/2019	1
East Tennessee Children's Hospital	24/07/2019	1
UT Southern / Simmons Cancer Center	28/09/2018	1
Roswell Park Cancer Center	18/11/2019	1
University of Southern California	20/08/2019	1
Dana Farber Cancer Center	24/08/2018	1
Broward HealthCare	10/01/2020	1
LA Biomedical Research Institute at Harbor- UCLA	2/07/2019	1
Dayton Children's Hospital	6/03/2020	1
Mayo Clinic	26/03/2019	1
Advocate Children's Hospital – Oak Lawn	20/09/2019	1
Loma Linda University Cancer Center	29/04/2019	1
University of Iowa/Holden Comprehensive Cancer Center	19/04/2019	1
Presbyterian Hospital New Mexico	05/08/2020	1
Saint Mary's Hospital	16/08/2018	1
Hackensack University Medical Center	13/11/2018	1
Providence Sacred Heart Medical Center and Children's Hospital	30/11/2018	1
Dell Children's Medical Center	12/12/2018	1
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Additional Blood Collections for Translational Research

A reminder that the current ANZ protocol includes two additional blood collection timepoints for translational research. 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) and send the completed forms to **p3bep.study@sydney.edu.au** after each collection.

Change in Study Email Address

Please note that the email address for the study inbox has changed. Contact us at **p3bep.study@sydney.edu.au** for all study-related questions going forward. For any sponsor queries, please continue to email **trials@anzup.org.au**.

Children's Oncology Group (COG), led by Dr Farzana Pashankar, now has 142 sites with IRB approval and 43 patients enrolled across the US. COG is also facilitating recruitment at adult cancer hospitals through the National Clinical Trials Network (NCTN). There are currently 2 NCTN sites actively recruiting.

Four UK sites recruited their first patients between February and July – Northern General Hospital, Aberdeen Royal Infirmary, University College Hospital, London, and The Christie.

CUH - UK		
Site Name	Activation Date	Participants
Royal Marsden Hospital	24/10/2018	11
University Hospital Southampton	15/05/2018	7
Cambridge University Hospital	16/03/2018	6
Royal Preston Hospital – Lancashire	11/01/2018	4
St James's University Hospital	10/07/2018	3
Beatson West of Scotland Cancer Centre	11/01/2018	3
Belfast City Hospital	21/06/2019	3
Velindre Hospital	26/04/2018	1
St Bartholomew's Hospital	05/10/2018	1
Bristol University Hospital	18/10/2017	1
Nottingham City Hospital	12/08/2019	1
Derriford Hospital – Plymouth	30/11/2017	1
Northern General Hospital	8/11/2018	1
Aberdeen Royal Infirmary	20/10/2020	1
University College Hospital, London	19/06/2018	1
The Christie	14/09/2020	1
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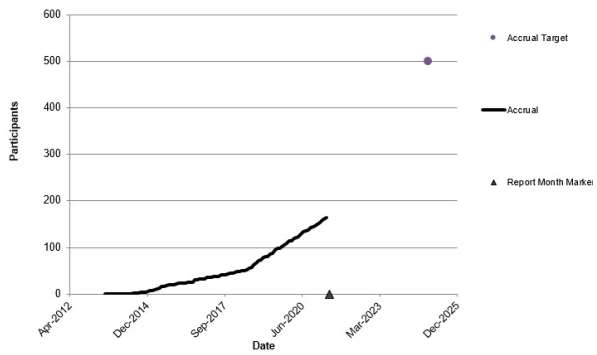
Overall recruitment summary



Response Data – Study-specific Reporting

A reminder that P3BEP requires a study-specific assessment of response criteria. The determination of response status is performed at 2 timepoints: initial response (30-42 days after the last dose of chemotherapy) and final response (6 months after randomisation, or at least 4 weeks after completion of all post-chemo surgery and other interventions, whichever occurs later. Refer to section 5.1.3 of the current protocol for further details).

Please ensure response is reported in the database as per the guidelines found in Appendix 6 of the current protocol. Response categories are summarised below:

1. Complete response

Including the following subcategories:

a. Complete response to chemotherapy

b. Complete response to chemotherapy and surgery - no viable germ cell malignancy found

c. Complete response to chemotherapy and surgery - viable germ cell malignancy fully resected

2. Partial response with negative markers

Defined as normalisation of serum tumour markers (AFP and HCG), with residual masses evident on imaging studies associated with one or more of the following:

a. It is deemed not technically possible or not advisable to surgically resect the residual masses, and/or

b. Patients only have partial resection of masses present, and where no viable cancer cells are detected in the surgical specimens (ie. histology shows only mature teratoma or necrosis), and/or

c. Surgical resection is not undertaken because of patient refusal.

3. Incomplete response

Defined as any response failing to meet the criteria of "Compete response" or "Partial response with negative markers" described above, and includes the following sub- categories:

a. Partial response with positive markers

b. Stable disease with positive markers

c. Progressive disease

Please note that as per protocol section 6.2.4, "it is mandatory that the *investigator* refers to the definition of responses (Appendix 6) when assigning final response." This task should *not* be delegated to the study coordinator, given the complexity of assessment of response in germ cell tumours. Thank you for assisting with this request.

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).

Phase 3 BEP key contacts

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- Trial information: https://www.anzup.org.au/content.aspx?page=trials-p3bep