

Phase 3 BEP Study News

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Welcome to the January 2022 Phase 3 BEP newsletter

Greetings and Happy New Year from the P3BEP team! We hope everyone is keeping safe, well and enjoyed a fantastic holiday period and had a chance to unwind with some well-deserved time off! A big thank you to all our incredible site teams (and international coordinating centres) for your continued dedication, hard work and effort with the P3BEP study during last year's turbulent events. We have now recruited 194 patients, with November being our best month yet (8 patients enrolled), including 28 patients enrolled since the last update mid last year, despite numerous lockdowns and hurdles faced by everyone.

Overview of study accrual and international collaborations

Study Accrual

Target Recruitment: 500

No. of patients randomised: 194

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	11
Princess Alexandra Hospital	16/06/2014	9
Nepean Hospital	10/03/2014	6
Royal Brisbane and Women's Hospital	08/04/2014	6
Auckland Hospital	12/12/2014	6
Prince of Wales Hospital	19/02/2014	4
Fiona Stanley Hospital	19/03/2014	4
Royal Adelaide Hospital	1/07/2014	4
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	2
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
		83

ANZ sites have collectively recruited 6 patients since the last update. Princess Alexandria Hospital has recruited 2 patients and Chris O'Brien Lifehouse, Auckland Hospital, Royal Adelaide Hospital, and Royal Hobart Hospital have each recruited 1 patient each.

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 are aiming to conduct the analysis by the end of February 2022. **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 following up with overdue forms and query requests for the remaining outstanding data entry. Please reach out if you have any questions: p3bep.study@sydney.edu.au

Many thanks for your assistance!

International Accrual

Site Name	Activation Date	Participants
Lucile Packard Children's Hospital Stanford University	4/12/2018	5
Memorial Sloan Kettering Cancer Center	26/03/2020	4
Washington University School of Medicine	9/08/2018	3
Rady Children's Hospital	6/09/2018	2
University of Texas Health Science Center at San Antonio	3/10/2018	2
Geisinger Medical Center	9/04/2019	2
Carolinas Medical Center/Levine Cancer Institute	13/05/2019	2
Advocate Children's Hospital - Oak Lawn	20/09/2019	2
NYU Winthrop Hospital	9/08/2018	1
Saint Mary's Hospital	16/08/2018	1
Dana Farber	24/08/2018	1
University of Minnesota/Masonic Cancer Center	7/09/2018	1
Roswell Park Cancer Institute	12/09/2018	1
Children's Hospital of Alabama	17/09/2018	1
Augusta University Medical Centre	12/10/2018	1
University of Wisconsin Hospital	16/10/2018	1
University of Mississippi Medical Centre	30/10/2018	1
Vanderbilt University	6/11/2018	1
UT Southwestern Simmons Cancer Centre	6/11/2018	1
Hackensack University Medical Center	13/11/2018	1
Providence Sacred Heart Medical Center and Children's Hospital	30/11/2018	1
East Tennessee Children's Hospital	30/11/2018	1
Dell Children's Medical Center of Central Texas	12/12/2018	1
Memorial Health University Medical Center	18/12/2018	1
Miller Children's and Women's Hospital Long Beach	13/03/2019	1
Mayo Clinic	26/03/2019	1
Kaiser Permanente Downey Medical Center	17/04/2019	1
University of Iowa/Holden Comprehensive Cancer Center	19/04/2019	1
Palmetto Health Richland	26/04/2019	1
Children's Healthcare of Atlanta - Egleston	29/04/2019	1
Methodist Children's Hospital of South Texas	22/05/2019	1
Loma Linda University Cancer Centre	29/04/2019	1
University of Southern California	20/08/2019	1
Broward HealthCare	16/01/2020	1
LA Biomedical Research Institute at Harbor-UCLA	2/07/2019	1
Dayton Children's Hospital	6/03/2020	1
Presbyterian Hospital New Mexico	5/08/2020	1
Tufts Children's Hospital	14/09/2021	1
Dartmouth-Hitchcock Medical Center	30/09/2021	1
Children's Hospital of Alabama	17/09/2018	1
Ann & Robert H. Lurie Children's Hospital	22/03/2019	1
Driscoll Children's Hospital	30/12/2020	1
Children's Hospitals and Clinics of Minnesota	30/07/2018	1
Total		57

InForm eCRF Completion Guidelines Update v4 to v5

The P3BEP eCRF completion guidelines were recently updated from v4 to v5 (07-Dec-2021). All sites should have received an email with the updated guidelines.

Summary of Changes:

New forms:

- TR Blood (refer to instructions on pg 16)
- End of Study (refer to instructions on pg 26)

Updated form:

- Biospecimens (Baseline visit) – TR Blood will no longer be collected on this form. This should be entered in the TR Blood form instead

Other administrative changes (i.e. update to help texts and auto-query rules) made to the several forms which will not affect current data entry requirements.

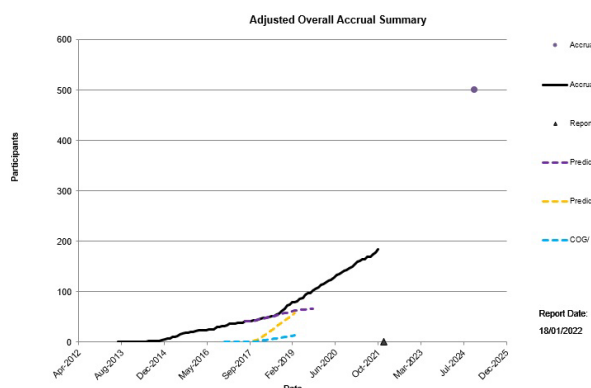
Please don't hesitate to contact the P3BEP team should you have any questions or did not receive the updated guidelines.

Children's Oncology Group (COG), led by Dr Farzana Pashankar, now has 143 sites with IRB approval and 57 patients enrolled across the US. 15 patients were recruited since the last update at USA sites.

University Hospital Southampton has recruited 4 patients since the last update. Beatson West of Scotland Cancer Centre, Royal Preston Hospital, Nottingham City Hospital and St. James' University Hospital have recruited 1 patient each. 54 patients enrolled across UK sites, with 8 patients recruited at UK sites since the last update.

Site Name	Activation Date	Participants
Royal Marsden Hospital	17/10/2018	11
University Hospital Southampton	15/05/2018	11
Cambridge University Hospital	5/05/2017	6
Royal Preston Hospital, Lancashire	11/01/2018	5
Beatson West of Scotland Cancer Centre	11/01/2018	4
St James University, Leeds	10/07/2018	4
Belfast City Hospital	21/06/2019	3
Nottingham University Hospital	28/09/2018	2
The Christie	14/09/2020	1
Northern General Hospital	8/11/2018	1
University College London Hospital	19/06/2018	1
St Bartholomew's Hospital	5/10/2018	1
Bristol University Hospital	18/10/2017	1
Derriford Hospital, Plymouth	19/06/2018	1
Aberdeen Royal Infirmary	20/10/2020	1
Velindre Hospital	26/04/2018	1
Total		54

Overall recruitment summary



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 v3.0) and scan through a copy of the completed forms to p3bep.study@sydney.edu.au after each collection.

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:

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

- It is deemed not technically possible or not advisable to surgically resect the residual masses, and/or
- 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
- Surgical resection is not undertaken because of patient refusal.

3. Incomplete response

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

- Partial response with positive markers
- Stable disease with positive markers
- 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).



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Phase 3 BEP key contacts

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- Trial information: <https://anzup.org.au/clinical-trial/p3bep/>