

Phase 3 BEP Study News

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Welcome to the December 2020 Phase 3 BEP newsletter

The P3BEP team would like to wish all of our collaborators a happy holiday season, and offer our thanks for your ongoing participation and efforts screening and recruiting patients to P3BEP throughout a difficult year. P3BEP has now recruited 145 patients, including 18 patients enrolled since the last update, and all collaborative groups have enrolled patients since June (10 US, 5 ANZ, 3 UK).

As we quickly approach the enrolment of our 150th patient, we are in the process of preparing for the interim analysis which will occur after we obtain response data for the first 150 patients. For this reason, we ask that you **please ensure data entry and query resolution is up to date in the InForm database**. Overdue forms and outstanding query requests are being sent to all sites monthly by our data management team. Please reach out if you have any questions: p3bep@ctc.usyd.edu.au.

We hope everyone has a safe and festive end to the year, and a happy new year ahead!

Study accrual and international collaborations

Study Accrual

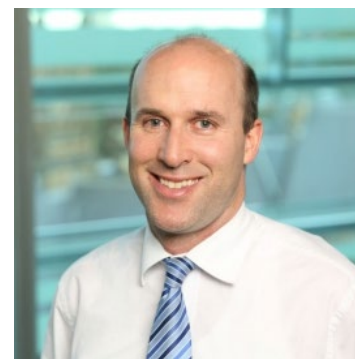
Target Recruitment: 500

No. of patients randomised: 145

Site Name	Activation Date	Participants to Date
Prince of Wales Hospital	19/02/2014	3
Calvary Mater Newcastle Hospital	04/03/2014	2
Nepean Hospital	10/03/2014	5
Concord Repatriation General Hospital	14/03/2014	1
Fiona Stanley Hospital	19/03/2014	4
Royal Brisbane and Women's Hospital	08/04/2014	5
Peter MacCallum Cancer Care	15/05/2014	11
Austin Health	11/06/2014	2
Princess Alexandra Hospital	16/06/2014	6
Royal Hobart Hospital	16/06/2014	1
Box Hill Hospital	19/06/2014	2
Royal Adelaide Hospital	1/07/2014	3
Macquarie Cancer Clinical Trials	21/08/2014	1
Christchurch Hospital	26/11/2014	2
Chris O'Brien Lifehouse	28/11/2014	8
Auckland Hospital	12/12/2014	5
Palmerston North Hospital	12/12/2014	1
Flinders Medical Centre	07/04/2015	1
Border Medical Oncology	20/07/2015	3
Starship Children's Hospital	18/09/2018	1
Queensland Children's Hospital	03/04/2019	1
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PHASE 3 BEP STUDY CHAIR

A/Professor
Peter Grimison



International Accrual

Site Name	Activation Date	Participants to Date
COG - USA		
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 Center	08/11/2018	1
Washington University Medical Center	13/08/2018	3
Rady Children's Hospital	05/09/2018	2
Augusta University Medical Centre	12/10/2018	1
Lucile Packard Children's Hospital Stanford	04/12/2018	5
Geisinger Medical Center	24/04/2019	2
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
University of Texas Health Science Center at San Antonio	28/02/2020	2
Mayo Clinic	26/03/2019	1
Advocate Children's Hospital – Oak Lawn	20/09/2019	1
Carolinas Medical Centre	13/05/2019	2
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
		41

Children's Oncology Group (COG), led by Dr Farzana Pashankar, now has 142 sites with IRB approval and 41 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.

Follow up visit "Months"

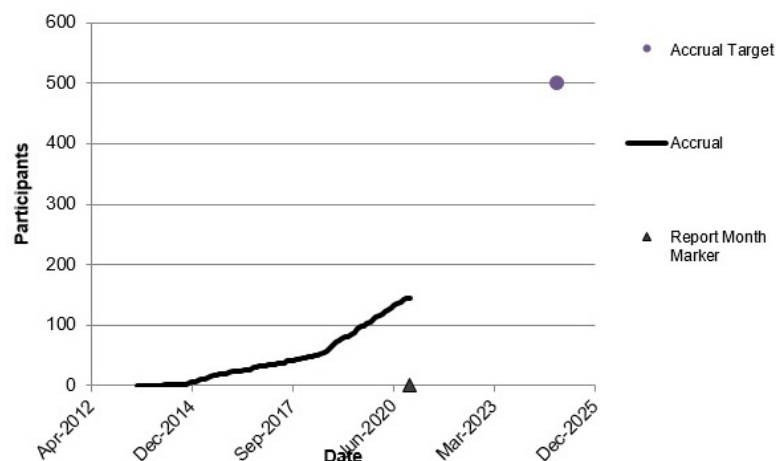
Follow up visits are 3 monthly, from 9 – 24 months from randomisation (i.e. at 9, 12, 15, 18, 21, 24), then 6 monthly from 24 – 60 months from randomisation (i.e. at 30, 36, 42, 48, 54, 60) and then annually thereafter until the study closes.

- All visits should be forecast from date of **randomisation**. If a follow up visit is missed, or the visit was delayed the next visit should be scheduled from the date of randomisation.
- Follow up 'months' are calculated based on the days in a year, one month = 365 days/12 (this equates to roughly 30.5 days).
- There is a ± 1 month window either side of the calculated visit date to perform the follow up visit.

CUH - UK	Activation Date	Participants to Date
Beatson West of Scotland Cancer Centre	11/01/2018	3
Royal Marsden Hospital	24/10/2018	10
St James's University Hospital	10/07/2018	3
Velindre Hospital	26/04/2018	1
St Bartholomew's Hospital	05/10/2018	1
University Hospital Southampton	15/05/2018	5
Bristol University Hospital	18/10/2017	1
Nottingham City Hospital	12/08/2019	1
Cambridge University Hospital	16/03/2018	4
Royal Preston Hospital – Lancashire	11/01/2018	4
Belfast City Hospital	21/06/2019	2
Derriford Hospital – Plymouth	30/11/2017	1
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The majority of UK sites paused recruitment at the beginning of the COVID-19 pandemic, but 3 patients have since been enrolled at Royal Marsden Hospital. The Christie Hospital was activated in September.

Overall recruitment summary



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).



**CHILDREN'S
ONCOLOGY
GROUP**

The world's childhood
cancer experts



**CANCER
RESEARCH
UK**

**CAMBRIDGE
CENTRE**



Cambridge University Hospitals **NHS**
NHS Foundation Trust

Phase 3 BEP key contacts

- Clinical trial operations E: p3bep@ctc.usyd.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://www.anzup.org.au/content.aspx?page=trials-p3bep>