

Phase 3 BEP Study News

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Welcome to the 2019 Q4 Phase 3 BEP newsletter

Thank you for your ongoing participation and efforts to screen and recruit to this randomised clinical trial of first-line chemotherapy for intermediate and poor-risk metastatic germ cell tumours. P3 BEP has now recruited 108 patients, achieving an important milestone of sufficient patients to trigger the first formal interim analysis by the IDSMC. 17 patients were recruited since the last update.

We are particularly grateful to our international collaborators in the UK and through the Children's Oncology Group, who have recruited 13 of the 17 patients recruited since the last update.

A/Prof Peter Grimison, Study Chair

Study accrual and international collaborations

Study Accrual

Target Recruitment: 500

No. of patients randomised: 108

Australia and New Zealand Accrual

Site Name	Activation Date	Participants to Date
Prince of Wales Hospital	19/02/2014	1
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	4
Peter MacCallum Cancer Care	15/05/2014	10
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	1
Royal Adelaide Hospital	1/07/2014	3
Macquarie Cancer Clinical Trials	21/08/2014	1
Christchurch Hospital	26/11/2014	1
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	1
Starship Children's Hospital	18/09/2018	1
TOTAL		59

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.



Australian Government
Cancer Australia



HREC submissions and approvals:

Protocol amendment V4.1 was approved by SLHD RPAH HRECS 18 June 2019 and sent to all ANZ sites on 19 June 2019. Please ensure you submit these documents to your local HREC/RGO per your local requirements and forward through approval to p3bep@ctc.usyd.edu.au when received.

International Accrual

Site Name	Activation Date	Participants to Date
COG		
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
Washington University Medical Center	13/08/2018	2
Rady Children's Hospital	05/09/2018	1
Augusta University Medical Centre	12/10/2018	1
Lucile Packard Children's Hospital Stanford	04/12/2018	3
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
Rosswell Park Cancer Center	18/11/2019	1
Beatson West of Scotland Cancer Centre	11/01/2018	3
Royal Marsden Hospital	24/10/2018	5
St James' Hospital - Leeds	10/07/2018	3
Velindre Hospital	26/04/2018	1
St Bartholomew's Hospital	05/10/2018	1
University Hospital Southampton	15/05/2018	4
Bristol University Hospital	18/10/2017	1
Nottingham University Hospital	12/08/2019	1
Cambridge University Hospital Paediatrics	16/03/2018	4
Royal Preston Hospital - Lancashire UK	11/01/2018	4
Belfast city Hospital	21/06/2019	2
Derriford Hospital Plymouth	30/11/2017	1
TOTAL		49

Other updates/useful Information

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.

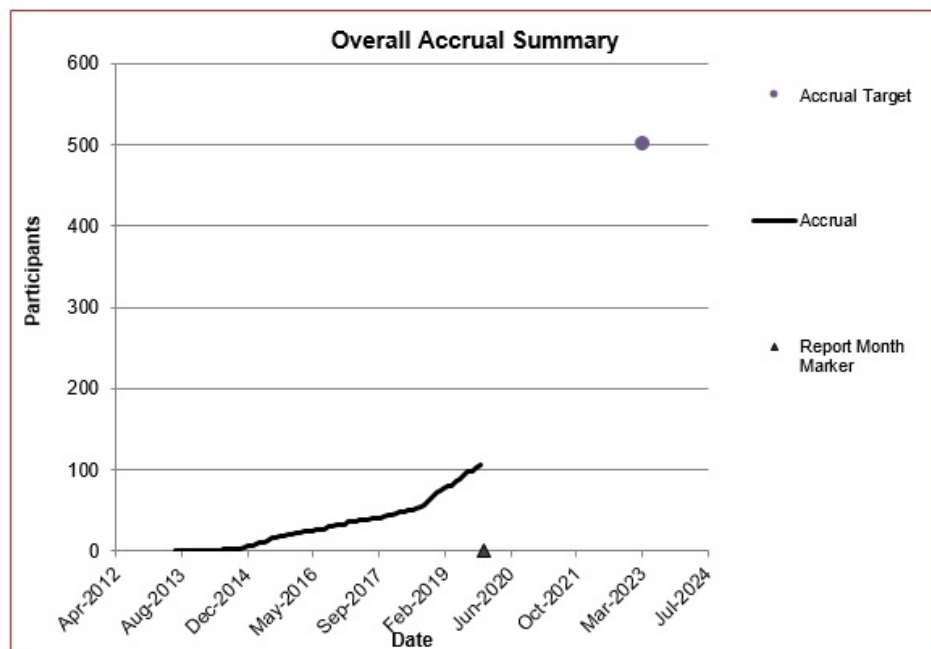
- All visits should be forecast from date of randomisation. If a follow up visit is missed, or the visit was delayed the next scheduled visit should be scheduled from the date of randomisation.
- Follow up 'months' are calculated based on the days in a year, one month = 365 days/12 (this equates to roughly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

The Cambridge Clinical Trial Centre (CCTC UK) team led by Dr Danish Mazhar have initiated 14 sites and recruited 30 patients since study activation in May 2017.

Children's Oncology Group (COG USA) led by Dr Farzana Pashankar now have 90 active sites and 129 sites with IRB approval since study activation, with 19 patients recruited across US sites. COG is also facilitating recruitment at adult cancer hospitals in the USA through the NCTN network. There is currently 1 NCTN site active for recruitment and 2 with IRB approvals.

Publication

Congratulations to Dr Shalini Subramaniam et al for the recent P3BEP Trials In Progress submission that has been accepted for poster presentation at ASCO GU 2020.



Study data

The stage 1 interim analysis for P3BEP is due to begin in early January 2020. In order to facilitate this analysis, please promptly enter data and respond to data queries in InForm within 2 weeks of queries being raised. We are aiming for the database to be up to date and clean by 15 January 2020.

Translational research

Sample collection

Blood and tissue from consenting P3 BEP participants will be collected for translational research studies.

Blood for translational research (optional) is collected at Baseline.

Process blood samples within 60 minutes of phlebotomy

Make a copy of the completed blood collection form, email to p3bep@ctc.usyd.edu.au

Store samples in their original snap-lock kit bag with the blood collection form – place in the large biopouch in freezer at -70°C or below.

- Enter all translational research blood collections into InForm database.
- Complete and email all blood collection forms to p3bep@ctc.usyd.edu.au

Thank you all for your tremendous efforts in recruiting for P3BEP in 2019! The P3BEP team wishes you and your family a safe and happy holiday season

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: nisha.rana@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>