

# Phase 3 BEP Study News

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## Welcome to the June 2020 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. P3BEP has now recruited 129 patients, including 21 patients recruited since the last update in December.

We are particularly grateful to our international collaborators in the UK and USA, who have recruited 16 of the 21 patients enrolled since the last update.

There have been some recent changes to the P3BEP team – we would like to warmly welcome Izabella Pokorski, taking over as Clinical Trial Operations Lead from Kate Ford, as well as Evan Buck, taking over as Trial Operations Coordinator from Amy Zhong. We wish Kate and Amy all the best and thank them for their many contributions to the P3BEP study.

## Study accrual and international collaborations

### Study Accrual

Target Recruitment: 500

No. of patients randomised: 129

### Australia and New Zealand Accrual

Site Name	Activation Date	Participants to Date
Prince of Wales Hospital	19/02/2014	2
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	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	2
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	3
Starship Children's Hospital	18/09/2018	1
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We are grateful to Cancer Australia for their financial support to conduct the study.



**Australian Government**  
Cancer Australia

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



CAMBRIDGE CENTRE



Cambridge University Hospitals NHS Foundation Trust

## International Accrual

Site Name	Activation Date	Participants to Date
<b>COG - USA</b>		
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	3
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	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	1
		<b>32</b>

Children's Oncology Group (COG USA), led by Dr Farzana Pashankar, now has 137 sites with IRB approval with 32 patients enrolled across US sites. COG is also facilitating recruitment at adult cancer hospitals in the USA through the NCTN network. There are currently 5 NCTN sites active for recruitment.

CUH - UK	Activation date	Participants to date
Beatson West of Scotland Cancer Centre	11/01/2018	3
Royal Marsden Hospital	24/10/2018	7
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
		<b>33</b>

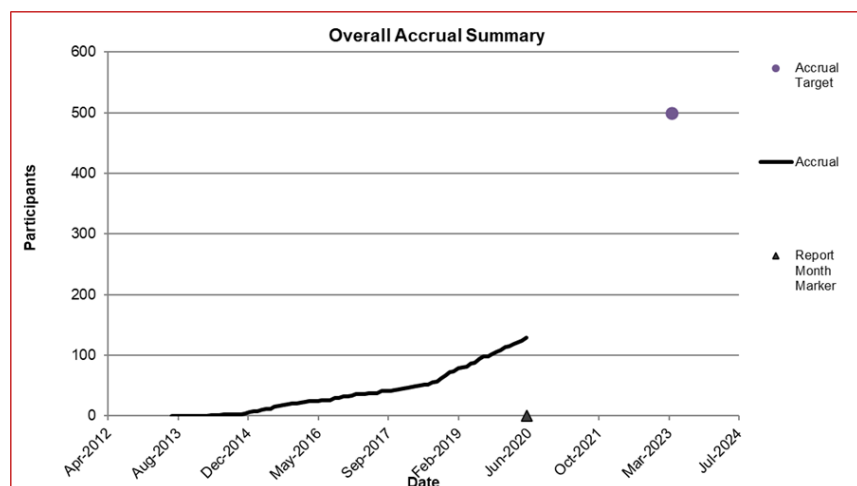
### Follow up visit “Months”

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  $\pm 1$  month window either side of the calculated visit date to perform the follow up visit.

### Database Upgrade

As previously communicated, the study InForm database was recently upgraded from v4.6 to v6.1. Although the database has an updated look and some navigational differences, the overall structure of the forms remains the same. Updated eCRF completion guidelines will be circulated to sites shortly. If you identify any issues with the database or if something does not seem to be working properly, please contact us to let us know. Please provide as much information as possible, including screenshots if applicable.



## Study data

The Open Query and Overdue Forms report was recently circulated to sites. Please review this report to ensure the database is up to date, and continue to regularly check the database for outstanding open queries. The next planned analysis will occur once we reach 150 patients enrolled – in order to facilitate this analysis, we ask that you please keep on top of data entry and query resolution. A friendly reminder that queries should be answered within 2 weeks of issue.

## COVID-19

It has been a stressful year for everyone, and we want to thank you for your continued support of this trial despite the difficult circumstances. Thank you for your help quickly implementing the COVID-specific guidance provided to you over the past couple of months – we really appreciate your cooperation. We trust that you are all keeping healthy and safe as restrictions begin easing throughout the region. As we return closer to “normal” operations, we ask that you please keep us updated with any changes to the situation at your site, including lifting of any recruitment holds or re-commencement of in-person visits. COVID-19 deviation logs will continue to be requested monthly along with site screening logs. Please contact us if you have any questions.

## 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. Please ensure blood samples are processed within 60 minutes of phlebotomy.

Make a copy of the completed blood collection form, email to [p3bep@ctc.usyd.edu.au](mailto: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](mailto:p3bep@ctc.usyd.edu.au)

***Thank you all for your tremendous efforts recruiting for P3BEP so far in 2020!***

## Phase 3 BEP key contacts

- Clinical trial operations E: [p3bep@ctc.usyd.edu.au](mailto:p3bep@ctc.usyd.edu.au) T: +61 2 9562 5000
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- Trial information: <https://www.anzup.org.au/content.aspx?page=trials-p3bep>