



ChILTERN

Children's Liver Tumour
European Research Network



**UNIVERSITY OF
BIRMINGHAM**



Inside this issue:

Welcome	1
Six Months	1
Sample Collections	3
Database	3
FAQs	4
Contact Details	4



Project No. 668596

Welcome

Welcome to the second edition of the PHITT Clinical Trial newsletter.

The Paediatric Hepatic International Tumour Trial (PHITT) is the single largest phase III clinical trial undertaken in paediatric liver cancer patients as a collaboration between the European Study Group for Paediatric Liver Tumours, Children's Oncology Group (COG) USA and Japan Children's Cancer Group (JCCG).

Six Months On

The Trial opened to recruitment in the UK on the 25th August 2017. Six months on we have 13 sites open in the UK. Leicester, Cardiff, Dublin, Birmingham, Belfast, GOSH (Great Ormond Street Hospital, London), King's College Hospital (London) and Southampton are yet to gain local approval and open. Three National Coordinating Centres (NCCs) are open, Republic of Ireland, Spain and Norway, with a further five to open this Summer.

A total of 12 patients have been recruited into the PHITT Clinical Trial so far, all from UK sites.

We have a dedicated Data Manager, Su Lee (S.W.H.Lee@bham.ac.uk) and we will have a dedicated Sample Manager, Duncan Gordon (D.H.Gordon@bham.ac.uk), soon.



STOP PRESS!! We have recruited our first international patient in Madrid, Spain! Patient registered 03/05/2018!

Six Months On - Trial Recruitment

The Trial has recruited more patients than expected in the given timeline! Thank you to all active sites for participating in the PHITT Trial, please continue to publicise this clinical trial, screen potential patients and recruit them if they prove eligible.

Site Name	Country	Site Activation Date	Date of First Patient Registration	Number of Patients Recruited
The Royal Marsden Hospital	UK	28-Sep-17	01-Nov-17	4
Bristol Royal Hospital for Children	UK	29-Nov-17	01-Dec-17	3
Royal Manchester Children's Hospital	UK	20-Sep-17	06-Nov-17	2
Leeds General Infirmary	UK	01-Feb-18	02-Mar-18	1
Nottingham Children's Hospital	UK	10-Jan-18	15-Jan-18	1
The Great North Children's Hospital, Newcastle	UK	21-Mar-18	23-Mar-18	1
Royal Aberdeen Children's Hospital	UK	11-Oct-17		0
Addenbrooke's Hospital, Cambridge	UK	25-Aug-17		0
Royal Hospital for Sick Children, Edinburgh	UK	16-Mar-18		0
Royal Hospital for Children, Glasgow	UK	12-Oct-17		0
Alder Hey Children's Hospital, Liverpool	UK	08-Dec-17		0
John Radcliffe Hospital, Oxford	UK	18-Dec-17		0
Sheffield Children's Hospital	UK	26-Jan-18		0
Oslo University Hospital	Norway	06-Mar-18		0
University Hospital Reina Sofia	Spain	14-Dec-17		0
Our Lady's Children's Hospital	Ireland	22-Nov-17		0

Six Months On - Case Report Forms

Thank you for all your beautifully completed forms returned in the last 6 months! Please keep it up and have a extra push to complete all outstanding data in time for a data review next month. Remember, we expect at least 80% return at all times, many thanks.

CRF Return Rate by Site	Nr. CRFs Returned	Nr. Of CRFs Outstanding	Total Nr. Of CRFs	Return Rate %
The Great North Children's Hospital, Newcastle	11	0	11	100.0%
Bristol Royal Hospital for Children	43	2	45	95.6%
Nottingham Children's Hospital	15	1	16	93.8%
Royal Marsden Hospital Sutton	55	6	61	90.2%
Royal Manchester Children's Hospital	34	5	39	87.2%
Leeds General Infirmary	6	6	12	50.0%
Grand Total	164	20	184	89.1%

Sample Collection

CHILDHOOD
LIVER
CANCER
NETWORK
collection

Thank you all for your continued support in ensuring that samples are taken at the correct time points and for returning sample forms. We work closely with the team at CLCN, Spain, to ensure that you have the materials you need to accurately and easily collect and store the labelled samples.



Especially important are snap frozen diagnostic samples - so please have a word with your laboratory staff to make sure they are happy! Let us know when any biopsies or surgeries are scheduled so that we can help where we can.

We welcome feedback on the sample collection process, so please get in touch at phitt@trials.bham.ac.uk to let us know what works and what doesn't!

Database News



Get prepared for training on the eRDC as the database is nearly ready to launch..!

We will let you know of a number of training sessions, which we hold through "Webex". Participants will receive a link to log into and can follow the demonstration on screen and over the phone.

We will provide a manual containing pictures of the database screens and instructions on how to access, complete and save CRFs.

The database will also be used to track sample kits, so you will be able to tell us which kits you have used and shipped.

The database is expected to be available soon - so look out for emails inviting you for training.

Thank you very much to CINECA for all of your hard work on the PHITT eRDC system, we look forward to using the final product soon.

FAQs

I can't take a 6hr post infusion sample as the patient/lab staff has gone home, what should I do? Samples should be taken at times indicated, but if a sample can be taken a bit late or early you should still collect it. The important thing is to record the dates and times accurately.

Should I take a post surgery blood sample? To clarify - samples should be taken at diagnosis (at some point prior to treatment), pre surgery, at end of treatment and also at recurrence, if applicable. The "Post Surgery" samples referred to in the lab manual are intended to be taken after end of treatment.

What about a Central Radiology Review? The trial will require a retrospective collection of scans for review. Further information will follow.

What should I do with sample tubes/pipettes etc. that are not used? Please hold on to any tubes etc. not used during sampling and return these to the CLCN for recycling when you batch return your samples.

Please get in touch with the Trial Team at phitt@trials.bham.ac.uk with any questions, we will be happy to help. Thank you all for your continued hard work on the PHITT Clinical Trial.

Contact The PHITT Trial Team

PHITT Clinical Trial Team

Children's Cancer Trials Team (CCTT)

Cancer Research UK Clinical Trials Unit (CRCTU)

Institute of Cancer and Genomic Sciences

University of Birmingham

Edgbaston

Birmingham

B15 2TT

☎: +44 (0)121 415 1061

✉: phitt@trials.bham.ac.uk

☎: +44 (0)121 414 9520

Team Leader: Nicola Fenwick

✉: N.Fenwick@bham.ac.uk | ☎: +44 (0) 121 415 8782 | ☎: +44 (0) 121 414 3700

Senior Trial Coordinator: Jennifer Laidler

✉: J.Laidler@bham.ac.uk | ☎: +44 (0)121 4151061 | ☎: +44 (0)121 414 3700.

Trial Coordinator: Steve Baker

✉: S.J.Baker.1@bham.ac.uk | ☎: +44 (0)121 4151061 | ☎: +44 (0)121 414 9520.

Trial Administrator: Duncan Gordon

✉: D.H.Gordon@bham.ac.uk | ☎: +44 (0)121 4158211 | ☎: +44 (0)121 414 9520.

Data Manger: Su Lee

✉: S.W.H.Lee@bham.ac.uk | ☎: +44 (0)121 4158211 | ☎: +44 (0)121 414 9520.