



ChiLTERN

Children's Liver Tumour
European Research Network



**UNIVERSITY OF
BIRMINGHAM**



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Project No. 668596

Welcome

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

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

One Year On

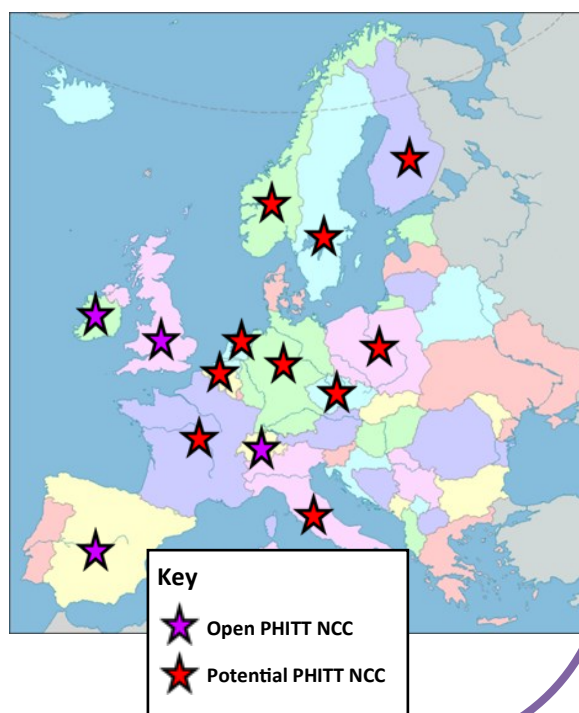
The Trial opened to recruitment in the UK on the 25th August 2017. Twelve months later there are now 15 sites open in the UK; Leicester, Cardiff, Great Ormond Street Hospital (London), King's College Hospital (London) and Southampton are still yet to open. There are now 4 National Coordinating Centres (NCCs) open: Republic of Ireland, Spain, Switzerland and Norway, with a further 8 to open soon.

A total of 26 patients has been recruited into the PHITT study so far, 20 from the UK and 6 from Spain, in all Treatment Groups except for Group E.

The main news is that the PHITT Trial Online Database, created by Cineca, is now live!! The team at the PHITT Office have been busy testing the database over several months and have now entered the data from all returned CRFs for you. From now on, hospital sites will be able to add PHITT data directly onto the database.

STOP PRESS!!

The PHITT Trial
Online Database is
now live!



One Year On - Trial Recruitment and CRF Return

The Table shows the recruitment figures and the percentage CRF return rate up to 31st August 2018. Since that date Leeds, Cambridge and Nottingham have recruited 3 more patients. We hope the database will improve CRFs return.

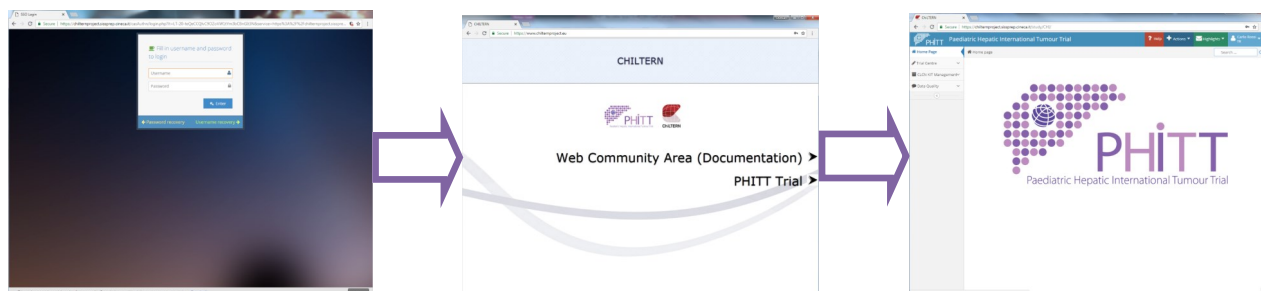
Thank you to all active sites for participating in the PHITT Trial, please continue to publicise this clinical trial, screen potential patients and recruit them if they prove eligible.

Site Name	Country	Site Activation Date	Number of Patients Recruited	Percentage CRF Return Rate by TNO
Alder Hey Children's Hospital, Liverpool	UK	08-Dec-2017	1	100%
Birmingham Children's Hospital	UK	11-May-2018	1	100%
Royal Manchester Children's Hospital	UK	20-Sep-2017	2	95%
The Great North Children's Hospital, Newcastle	UK	21-Mar-2018	1	88%
Bristol Royal Hospital for Children	UK	29-Nov-2017	3	86%
Royal Marsden Hospital, Sutton	UK	28-Sep-2017	4	75%
Addenbrookes Hospital, Cambridge	UK	25-Aug-2017	2	63%
Nottingham Children's Hospital	UK	10-Jan-2018	2	58%
Hospital Universitario 12 de Octubre, Madrid	Spain	24-Apr-2018	1	50%
Leeds General Infirmary	UK	01-Feb-2018	1	48%
Hospital Universitario Son Espases, Mallorca	Spain	18-Jul-2018	1	40%
Hospital Universitari Vall D'Hebron, Barcelona	Spain	25-May-2018	2	18%
Hospital Universitario de Cruces, Bizkaia	Spain	29-May-2018	1	0%
Hospital Universitario Virgen del Rocio, Sevilla	Spain	02-Jul-2018	1	0%

PHITT Trial Online Database

The PHITT Trial Online Database is now live and it enables you to register, allocate trial treatment and randomise patients, enter and complete Trial Data forms; CLCN Kit forms and Sample forms, record CLCN Sample Kits received and sample shipments; create and respond to eQueries (Data Clarifications) from the Trial Office.

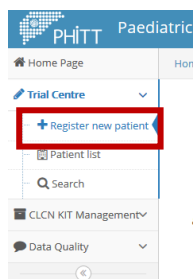
It can be accessed using the internet address: <https://www.chilternproject.eu>. Logging on will take you to the Chiltern Home Page, through which you can enter the database Home Page. The following pages show you how to register, allocate treatment and randomise a new patient. Please see the **PHITT Trial Online Database User Manual** for more details.



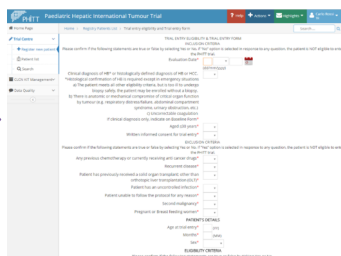
PHITT Trial Online Database—New Patient

Remember from now on all Forms need to be completed on the PHITT Trial Online Database

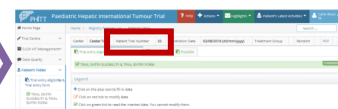
Click on *Register new patient* on the Home Page.



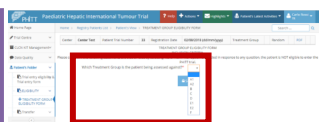
Complete combined Trial Entry Eligibility and Trial Entry Form.



Once completed, the system will create a unique Trial Number for the patient displayed on the Patient's View Page.



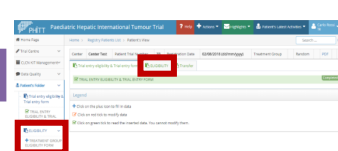
Use the drop-down list to allocate the Treatment Group to the patient.



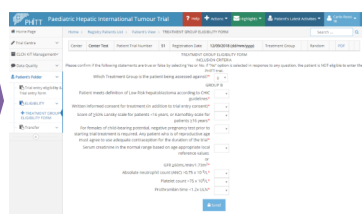
Click on the Treatment Group Eligibility Form.



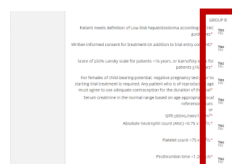
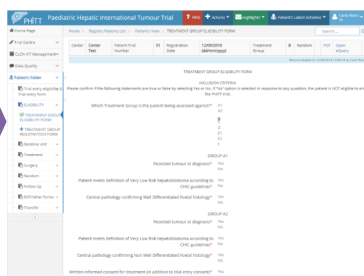
After registration, click on the next tab ('Eligibility').



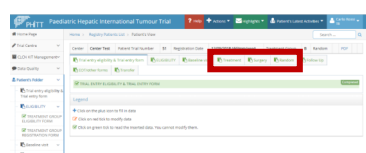
The relevant Treatment Group Eligibility Form— e.g. Group B.



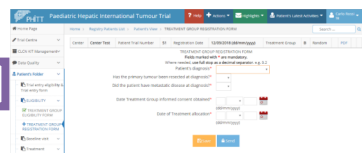
Once completed, click **Send**, the form will show all Treatment Groups, with the completed answers appearing in bold.



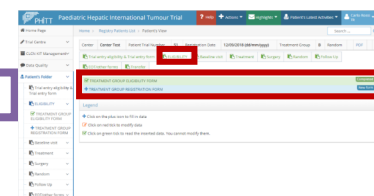
The system will now show more Form tabs (e.g. Treatment Forms), ready to be completed by you.



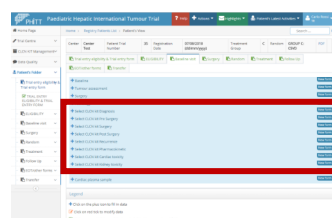
Click on and complete this Form, to register the patient for treatment.



Return to 'Patient's View' and click on the 'Eligibility' tab. The Treatment Group Registration Form has now appeared.



Remember—Before completing any Sample forms, allocate the CLCN Kit Codes to the various treatment time point forms on the Baseline tab.



PHITT Trial Online Database—Randomisation

The 'Random' tab gives the Randomisation Form for the allocated Treatment Group. The Randomisation Form must be completed to continue completing any further forms, even if the patient is allocated a non-randomised arm (i.e. Group D1).

After clicking on the form and opening it, there is a drop-down with the options 'Yes' or 'No'.

Answering 'No' should only be used if in the case of 'Patient refusal' or 'Medical conditions'.

Answering 'Yes' gives a drop-down with two options: 'Web system' (using database) or 'On phone (emergency Randomisation)' (only used by Trial Office).

The database will display the randomisation questions if necessary and automatically allocate a randomisation arm to the patient.

PLEASE REFER TO THE PHITT TRIAL ONLINE DATABASE USER MANUAL FOR MORE DETAILS

Contact The PHITT Trial Team

PHITT 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, UK.

✉: phitt@trials.bham.ac.uk ☎: +44 (0)121 415 1061 📞: +44 (0)121 414 9520

Team Leader (CCTT-A): 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 (UK): Steve Baker ✉: S.J.Baker.1@bham.ac.uk | ☎: +44 (0)121 4151061 | 📞: +44 (0)121 414 9520.

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

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