



ChiLTERN

Children's Liver Tumour
European Research Network

@Cancer Research UK Clinical Trials Unit
CRCTU

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Project No. 668596

Welcome

Welcome to the **fifth** edition of the PHITT Clinical Trial newsletter.

After being open for nearly 2 years the PHITT Trial is coming on strong now with increased recruitment due to more sites opening in the various participating countries. With more countries about to open and more wanting to join the trial, let's **do all we can to ensure** the patient recruitment target is met over the next year and a half. Keep up the excellent work in making the PHITT Trial a success.

21 Months On

There are now **20 sites open** in the UK with only Cardiff to open.

With **7 NCC Countries** open to recruitment: Belgium (7 sites open), France (25 sites open), Republic of Ireland (1 site open), The Netherlands (1 site open), Norway (1 site open), Spain (14 sites open) and Switzerland (9 sites open) with the Czech Republic, Germany, Poland, Italy and Sweden to open soon. We are also pleased to welcome Finland and Austria in the coming months.



A total of **56 patients** have been recruited into the PHITT study so far, 35 from the UK, 8 from Spain, 7 from France, 3 from Norway, 2 from Switzerland and 1 from Belgium in all Treatment Groups (A to F) and including Trial Entry Only.

Breaking news is that Israel would like to join as the first non-European NCC, and it will also be the first time that they will join a University of Birmingham sponsored Cancer Clinical Trial.

STOP PRESS!!
Austria, Finland and
Israel to join as
NCCs.



Key

-  Open PHITT NCC
-  Planned PHITT NCC

21 Months On - Trial Recruitment and Data Return

The Table shows the recruitment figures and the percentage CRF return rate up to 17th May 2019. Now that the PHITT Trial Online Database is open, the percentage CRF return keeps improving. Please continue to complete Case Report Forms and Sample Forms on the PHITT Trial Online Database.

Thank you to all active sites for participating in PHITT, please continue to offer, screen, consent and recruit potential patients if they prove eligible.

Site Name	Country	Site Activation Date	Number of Patients Recruited	Percentage CRF Return Rate
Institut Curie, Paris	France	17-Apr-2019	1	100%
Royal Victoria Infirmary, Newcastle upon Tyne	UK	21-Mar-2018	1	97%
Royal Manchester Children's Hospital	UK	20-Sep-2017	4	96%
Bristol Royal Hospital for Children	UK	29-Nov-2017	3	95%
Royal Belfast Hospital for Sick Children	UK	31-May-2018	1	93%
Alder Hey Children's Hospital, Liverpool	UK	08-Dec-2017	2	92%
Hospital Universitario Politecnico La Fe, Valencia	Spain	20-Dec-2018	1	92%
Hospital Universitario de Cruces, Bizkaia	Spain	29-May-2018	1	92%
John Radcliffe Hospital, Oxford	UK	18-Dec-2017	2	88%
Queen's Medical Centre, Nottingham	UK	10-Jan-2018	4*	87%
Hospital Universitario 12 de Octubre, Madrid	Spain	24-Apr-2018	1	87%
Royal Marsden Hospital, Sutton	UK	28-Sep-2017	5	82%
Hospital Universitario Virgen del Rocío, Sevilla	Spain	02-Jul-2018	2	81%
Oslo University Hospital	Norway	06-Mar-2018	3	79%
Birmingham Children's Hospital	UK	11-May-2018	2	79%
Centre Hospitalier Universitaire (CHU) de Rennes	France	06-Nov-2018	1	75%
Addenbrooke's Hospital, Cambridge	UK	25-Aug-2017	4	74%
Hospital Universitario Son Espases, Mallorca	Spain	18-Jul-2018	1†	71%
Institut Gustave Roussy, Paris	France	31-Jan-2019	1	67%
Leeds General Infirmary	UK	01-Feb-2018	5	63%
Sheffield Children's Hospital	UK	26-Jan-2018	1	60%
Centre Hospitalier Universitaire Vaudois, Lausanne	Switzerland	02-Oct-2018	1	58%
Centre Oscar Lambret, Lille	France	29-Mar-2019	1	50%
Hospital Universitari Vall D'Hebron, Barcelona	Spain	25-May-2018	2	50%
Hospital Couple Enfant – CHU Grenoble	France	08-Jan-2019	2	43%
Universitäts-Kinderspital beider Basel	Switzerland	08-Oct-2018	1	43%
Centre Hospitalier Universitaire (CHU) Timone, Marseille	France	05-Dec-2018	1	36%
St James's University Hospital, Leeds	UK	14-Dec-2018	1	33%
Cliniques Universitaires Saint-Luc, Brussels	Belgium	01-Feb-2019	1	25%

*One of these patients has now been transferred to Leicester Royal Infirmary, UK

†This patient has now been transferred to Hospital Universitari Vall D'Hebron, Barcelona, Spain

Our NCCs will have noticed that our International TC, Su Lee, is no longer chasing them for updates or contracts. Su is now the TC on another Children's Team trial and I'm sure everyone will join the PHITT team in thanking Su for her outstanding contribution over the last 2 years and wish her well with her new trial.

Collecting Patient Samples for the PHITT Trial

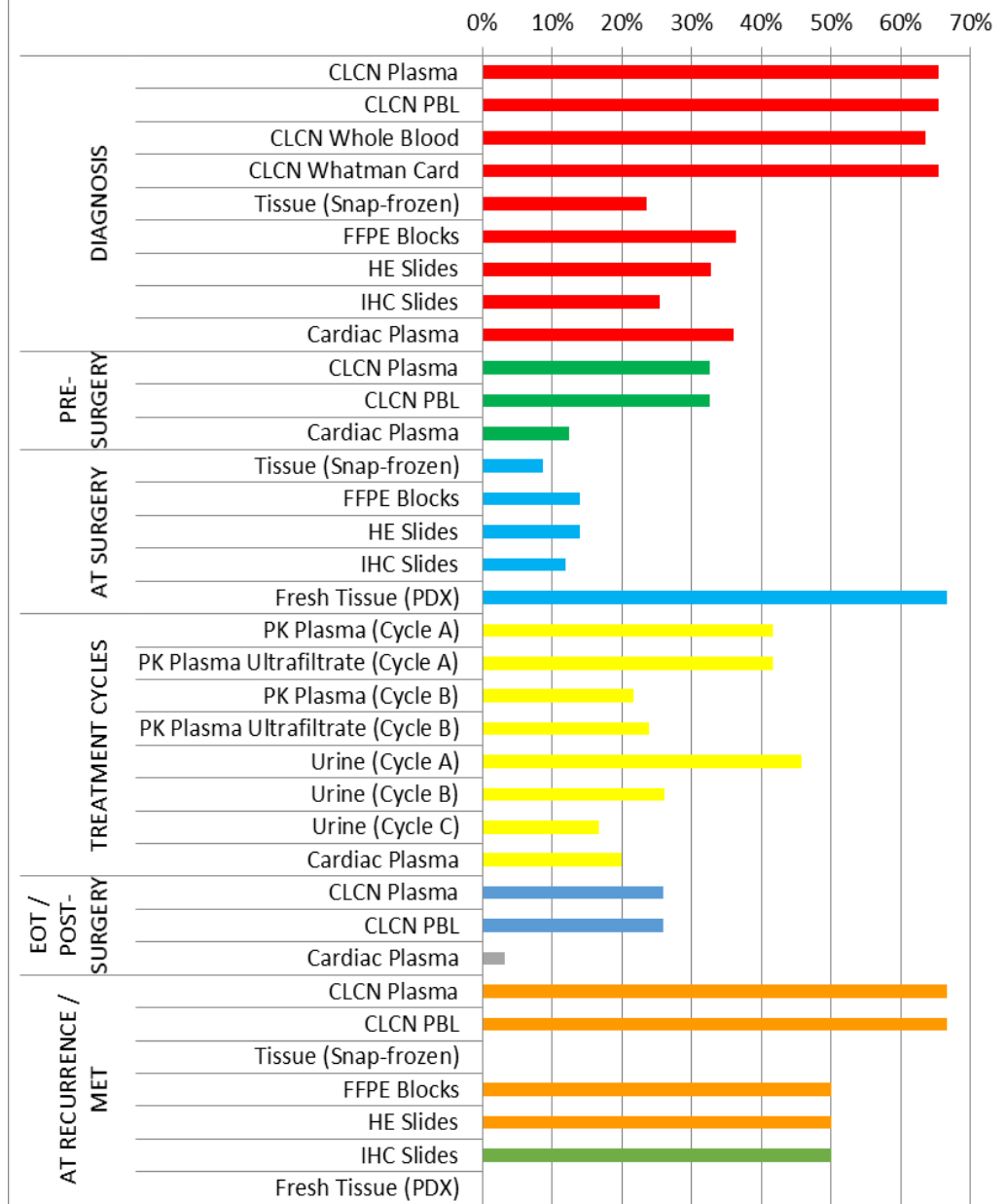
The PHITT trial underpins two major studies in the evaluation of biologically relevant factors: the **Biological and Pathological (Biology) Study** and the **Pharmacokinetics, Pharmacogenetics and Toxicity Biomarker (Toxicity) Study**.

Even though the collection of patient samples is not mandatory, the aim is to collect as many types of patient samples (frozen and fresh tissue, FFPE Blocks, HE/IHC slides, blood, plasma and urine) as possible to provide a comprehensive collection.

Please...

- try and collect as many patient samples as possible from the various collection time-points. For PK samples, the earlier time-points are most important.
- record the kit codes used on the Select CLCN forms on the database
- keep any used tubes and labels to return for re-use
- record the details on the Sample forms on the database, especially Diagnostic Biopsy and Blood Sample forms
- complete the Surgery (Biopsy) form on the Baseline Visit tab, so that the Biopsy Sample form appears in the same tab
- when shipping samples, include a PHITT Sample Shipment Form and fax/email a copy to the PHITT Trial Office

SAMPLES TAKEN AT TIME POINT AS A % OF RELEVANT PATIENTS



The graph shows the percentage of samples taken so far in the trial (up to 22-May-19). It displays the different treatment time-points dependant on whether it is relevant to a particular patients' treatment.

A simplified Lab manual will be distributed to help.

NEW FUNCTIONS IN THE DATABASE

The database was updated in April to match the Protocol v3.0 and to address some of the problems we have noticed since the database was launched last Sep 2018. The main changes are described below.

We would like to collect **Audiology Reports** where we can. You can do this through a button now added to the database, when you complete the result.

Baseline Form

“was the diagnosis clinical only” and the reasons (referred to on the Trial Entry Eligibility Form)

Added HIV result (if available)

You now only record GRF if serum creatinine is *above* normal range (instead of *outside* normal range)

End of Treatment form

Added ability of upload Audiology report

Surgery form

Added option to upload image from paper CRF/ patient’s notes

Added “Date donor became available”

Treatment form

Questions “Was dexrazoxane used” and “Was STS used” added if relevant to patient pathway

You now only record GRF if serum creatinine is *above* normal range (instead of *outside* normal range)

Treatment group Eligibility updated to match Protocol v3.0

Pathology form

added “Indicate main epithelial variant”

Simplified histology questions and Mirror block section removed

Follow Up—Tumour evaluation form is not required at Follow up

You can now arrange **Pathology reviews** through the database!

New tab on patient view — Pathology Review

Diagnostic Review form

By indicating on the database, the review can be completed online. NB—slide images can be uploaded for review, or sent by post. Please see Database Manual—for Pathologists for further details.

Complete form indicating if patient diagnosis should be reviewed urgently or standard

Contact the PHITT Trial Team

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