



ChiLTERN

Children's Liver Tumour
European Research Network

@Cancer Research UK Clinical Trials Unit
CRCTU

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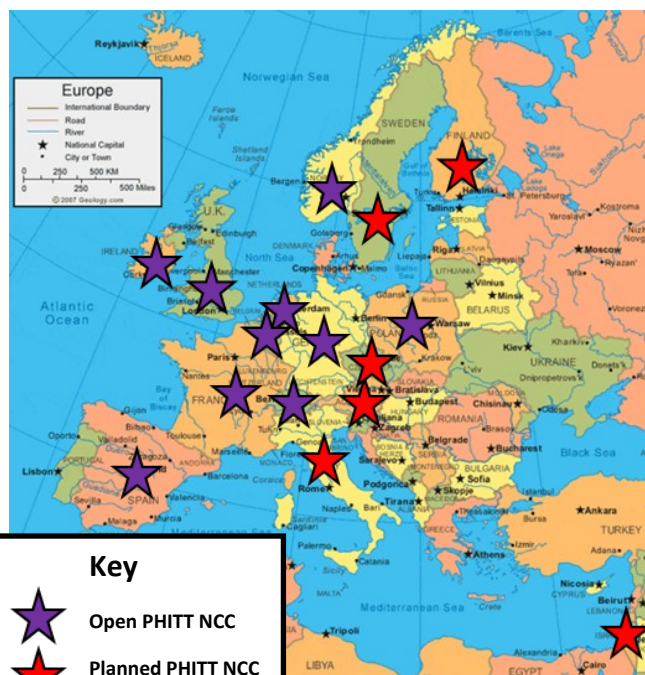
Welcome

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

The PHITT Trial has now been open to recruitment for 2 years. We would like to congratulate all open sites and National Coordinating Centres (NCCs) for the hard work, which has now put the trial in a good position. July 2019 was our best month so far, with a record number of 9 patients recruited. Please keep up the excellent work in making the PHITT Trial a success.

2 Years On

Figure 1. A Map of Europe Showing PHITT Trial NCCs



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

8 NCC Countries open to recruitment: Belgium (7 sites open), France (26 sites open), Germany (1 site open), Republic of Ireland (1 site open), The Netherlands (1 site open), Norway (3 sites open), Poland (1 site open), Spain (14 sites open) and Switzerland (9 sites open). Austria, the Czech Republic, Finland and Israel are to open soon.

A total of **75 patients** has been recruited into the PHITT study so far, 37 from the UK, 15 from France, 11 from Spain, 3 from Norway, 3 from Switzerland, 3 from Belgium, 2 from The Republic of Ireland and 1 from The Netherlands, in all Treatment Groups (A to F).

We welcome all of the new NCCs and look forward to their contributions towards helping the trial to reach its target.

STOP PRESS!!

Germany and Poland
have now opened as
NCCs.

2 Years On - Trial Recruitment and Data Return

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

The Table shows the recruitment figures and the percentage CRF return rate up to 14th August 2019. The percentage CRF return keeps improving thanks to the PHITT Trial Online Database. Please continue to complete Case Report Forms and Sample Forms (with their accompanying CLCN Kit Forms) on the PHITT Trial Online Database. We aim to have a minimum 80% CRF return rate from each site.

Table 1. Highest and Lowest Percentage CRF Return Rates by Site

Site Name	Country	Site Activation Date	Number of Patients Recruited	Percentage CRF Return Rate
Universitäts Kinderspital, Zurich	Switzerland	02-Oct-2018	1	100%
Prinses Maxima Centrum voor Kinderoncologie, Utrecht	The Netherlands	05-Apr-2019	1	100%
Leicester Royal Infirmary	UK	01-Feb-2019	1	100%
Royal Victoria Infirmary, Newcastle upon Tyne	UK	21-Mar-2018	1	100%
Hopital Armand-Trousseau, Paris	France	21-Dec-2018	1	100%
Bristol Royal Hospital for Children	UK	29-Nov-2017	3	98%
Royal Belfast Hospital for Sick Children	UK	31-May-2018	1	95%
Royal Marsden Hospital, Sutton	UK	28-Sep-2017	5	94%
Our Lady's Children's Hospital, Dublin	Republic of Ireland	22-Nov-2017	2	94%
Centre Hospitalier Universitaire (CHU) Timone, Marseille	France	05-Dec-2018	1	94%
Hospital Universitario Virgen del Rocío, Sevilla	Spain	02-Jul-2018	2	93%
Hospital Universitario Politécnico La Fe, Valencia	Spain	20-Dec-2018	1	92%
Royal Manchester Children's Hospital	UK	20-Sep-2017	5	90%
Queen's Medical Centre, Nottingham	UK	10-Jan-2018	3	89%
Sheffield Children's Hospital	UK	26-Jan-2018	1	88%
John Radcliffe Hospital, Oxford	UK	18-Dec-2017	2	87%
Hospital Universitario de Cruces, Bizkaia	Spain	29-May-2018	1	83%
Hospital Universitario 12 de Octubre, Madrid	Spain	24-Apr-2018	1	83%
Institut Curie, Paris	France	17-Apr-2019	2	79%
Alder Hey Children's Hospital, Liverpool	UK	08-Dec-2017	2	78%
Leeds General Infirmary	UK	01-Feb-2018	5	78%
Addenbrooke's Hospital, Cambridge	UK	25-Aug-2017	4	77%
Centre Hospitalier Universitaire (CHU) de Rennes	France	06-Nov-2018	1	73%
Birmingham Children's Hospital	UK	11-May-2018	2	70%
Hospital Couple Enfant – CHU, Grenoble	France	08-Jan-2019	2	64%
Institut Gustave Roussy, Paris	France	31-Jan-2019	1	60%
Oslo University Hospital	Norway	06-Mar-2018	3	57%
Centre Hospitalier Universitaire Vaudois, Lausanne	Switzerland	02-Oct-2018	1	56%
Hospital Universitari Vall D'Hebron, Barcelona	Spain	25-May-2018	3	54%
Hospital Sant Joan de Deu, Barcelona	Spain	18-Mar-2019	2	50%
Universitäts-Kinderspital beider, Basel	Switzerland	08-Oct-2018	1	50%
Hopital Morvan, Brest	France	19-Dec-2018	1	50%
Centre Hospitalier Universitaire (CHU) de Poitiers	France	09-May-2019	1	44%
Universitair Ziekenhuis, Gent	Belgium	11-Apr-2019	1	42%
Cliniques Universitaires Saint-Luc, Brussels	Belgium	01-Feb-2019	2	36%
St James's University Hospital, Leeds	UK	14-Dec-2018	1	32%
Centre Oscar Lambret, Lille	France	29-Mar-2019	1	28%
Centre Hospitalier Universitaire (CHU) de Rouen	France	29-May-2019	1	-

Correcting Mistakes on the Database

When you have completed an electronic Case Report Form (eCRF) on the PHITT Trial Online Database and have clicked on the 'Send' button and you realise afterwards that you have made a mistake, the data can still be changed using the eQuery function (see Section 6, Pages 23—27 of the Database User Manual).

- Open the eCRF that requires changing and click on the Open eQuery link in the top right hand corner

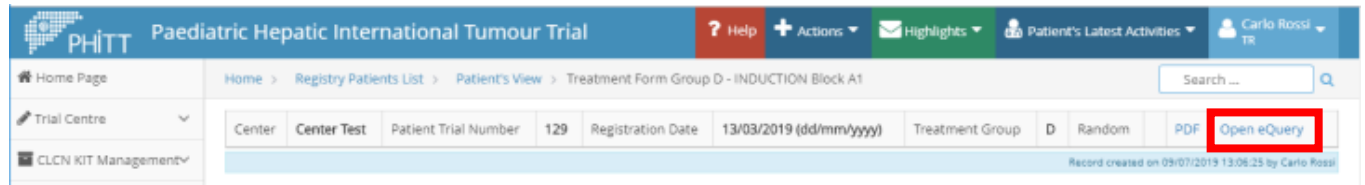


Figure 2. Opening eQuery on database

- Click on the blue pencil icon next to the data item you would like to change. You will now be able to change the data item. Also enter a response in the Comment box that appears on the right

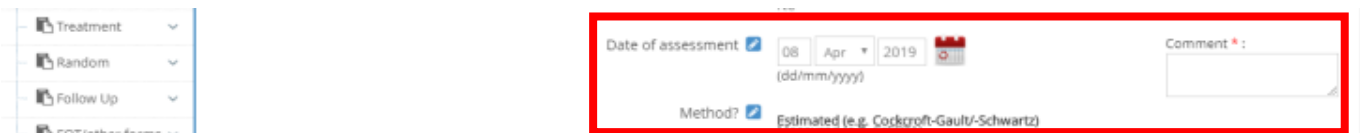


Figure 3. Changing data item on database

- Click on the Integrate Form button at the bottom of the form once the data item has been modified and the Comment box has been completed.
- The changed data item will now appear with a Black Speech balloon and a comment next to it and the relevant eCRF will now appear on the Patient's View page with a Red Speech Bubble next to it.



Figure 4. Data item changed on database and ready to be checked

- The changed data item will now appear in the Answered eQueries option in the Data Quality section as an eQuery. The Lead Study Coordinator will check and accept the changed data item and the eQuery will then appear in the Closed eQueries option to show it has been changed.

Online Survey for the PHITT Trial Online Database

An online user survey for the PHITT Trial Online Database has been created, so that users can have their say on how they find it to use. Please click on the link below to connect to it:

[PHITT Trial Online Database Survey](https://forms.office.com/Pages/ResponsePage.aspx?id=BQOu_B0nOkYuuaU1cxN_KR0oxZ9ERt5OuzYzGRCKFFRUNUczMVhJT1hETUHVkFOSEpQQk9YUjU3NC4u)

(https://forms.office.com/Pages/ResponsePage.aspx?id=BQOu_B0nOkYuuaU1cxN_KR0oxZ9ERt5OuzYzGRCKFFRUNUczMVhJT1hETUHVkFOSEpQQk9YUjU3NC4u)

Completing the survey only takes a few minutes and we would welcome as many database users as possible to complete the survey, anonymously if preferred, so that they can help improve it.



More FAQs

Q. I have a patient on Treatment Group B who did not have surgery after 2 cycles of chemotherapy treatment and therefore automatically been assigned to Group B2. Where are the further treatment forms?

A. Even though the patient has not been 'randomised' into a treatment arm, the Randomisation Form on the Random tab of the Patients' Home Page will still need completing, so that the further treatment forms will appear in a new tab, after it has been sent. (This also applies to patients in Treatment Group D).

Q. One of the mandatory questions (with a red star) on a form requires a numerical value as an answer, but I do not know the answer and the answer box refuses letters to be typed in, such as ND (Not Done) or NK (Not Known). What do I do?

A. To get around this, whether the form is a Case Report Form or a Sample Form, give the answer as '00' (zero, zero), which will be the equivalent of 'Not Known'.

Q. I have noticed that there is a new tab on the Patients' Home Page called Pathology Review. Do I need to complete any of these forms?

A. Yes. The Diagnostic Review Form (Local) needs to be completed, stating whether the Pathology Review is 'Urgent' or 'Standard (non-urgent)'. This will create new forms in the tab to be completed: National Pathology Form (diagnostic) and International Pathology Form (diagnostic). When the Pathology Review is marked 'Urgent', the International Pathology Reviewer receives an automatic email informing them of a new Rapid Central Pathology Review patient. (See Section 7 of the PHITT Protocol, Version 3.0, for further details on 'urgent' or 'non-urgent').

Q. I have heard there are no more Toxicity Study CLCN Sample Kits (PK Plasma, Cardiac Plasma and Urine Samples) available to be shipped to sites and NCCs. Our site has run out of them. What do I do?

A. Contact the PHITT Trial Office on phitt@trials.bham.ac.uk and we will endeavour to find spare CLCN Sample Kits at other sites that can be transferred to your site. Failing that, the Northern Institute for Cancer Research (NICR), Newcastle University, UK, that runs the Toxicity Study, has stated that sites can use their own standard hospital tubes to collect samples and they will supply Centrifree tubes for the centrifuged samples. IGTP will then assign CLCN Kit Codes to these 'new' Kits on the database. Contact nicr-clin-sample@ncl.ac.uk for further details. A new supply of kits is currently being sourced to resolve the issue.

Q. I have noticed that the EDTA Blood Sample tubes as part of the CLCN Sample Kits have passed their expiry dates. Can I still use them?

A. IGTP, Barcelona, Spain, who supply the CLCN Sample Kits, have stated that the expiry dates do not matter.

Contact the PHITT Trial Team

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