



PHITT Newsletter

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INSIDE THIS ISSUE:

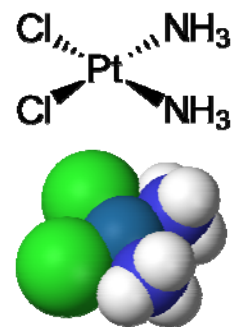
Welcome	1
UK Sites	2
European National Coordinating Centres (NCCs)	3
Recruitment	3
PHITT Sample Kit	4
ChiLTERN Collaborators Meeting	4
Contact Details	4

Dear All,

Welcome to the first edition of the PHITT newsletter.

The Paediatric Hepatic International Tumour Trial (PHITT) opened to recruitment in the UK on the 25th August 2017. It will be the single largest phase III clinical trial undertaken in paediatric liver cancer patients as collaboration between the European Study Group for Paediatric Liver Tumours, Children's Oncology Group (COG) USA and Japan Children's Cancer Group (JCCG).

It will investigate the current therapies for two types of liver cancer in children and young adults, called Hepatoblastoma (HB) and Hepatocellular Carcinoma (HCC). These liver cancers are rare and they account for 1% of paediatric cancers. Current treatment regimens can expose children and young adults to significant toxicities, e.g. cisplatin-induced hearing loss, kidney problems, heart problems and secondary leukaemia.



Cisplatin



In low risk patients, the trial will look at whether the amount of therapy given can be reduced and still be as effective in treating the disease. It will also look at using new therapies where prognosis is

poor. Patients will be allocated treatment according to the characteristics of their disease and will be put into one of six Treatment Groups.

An important part of the trial is the collection of tissue and blood samples from all of the patients, to look at the biology of the disease and create the world's largest repository of samples from these patients.



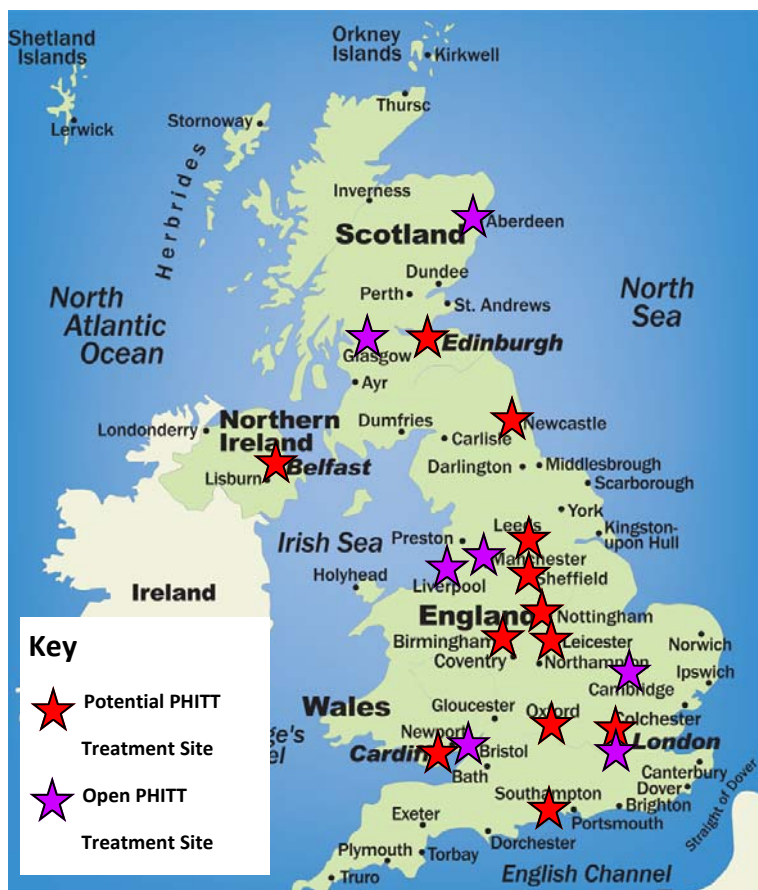
The study hopes to recruit 300 patients across Europe aged between 0 and 30 years over a period of 3 - 4 years. It is anticipated that at least 13 countries in Europe will participate in the trial.

UK SITES

There are 19 hospital sites in the UK that have agreed to be part of the PHITT Clinical Trial, from right across the country, so that children and young adults will now have access to trial treatment from anywhere in the UK. There is also an extra hospital site (King's College Hospital, London) that will just undertake surgery on the patients for several hospital sites.

So far there have been 12 Site Initiation Visits and 7 of these sites have now opened.

These are:



Addenbrooke's Hospital, Cambridge,
opened on 25-Aug-2017;

Royal Manchester Children's Hospital,
opened on 20-Sep-2017;

Royal Marsden Hospital, Sutton,
opened on 28-Sep-2017;

Royal Aberdeen Children's Hospital,
opened on 11-Oct-2017;

Royal Hospital for Children, Glasgow,
opened on 12-Oct-2017;

Bristol Royal Hospital for Children,
opened on 29-Nov-2017;

Alder Hey Children's Hospital, Liverpool,
opened on 08-Dec-2017.

Cambridge University Hospitals 
NHS Foundation Trust

 Royal Manchester
Children's Hospital
Central Manchester University Hospitals 
NHS Foundation Trust

The ROYAL MARSDEN
NHS Foundation Trust


NHS
Grampian


NHS
Greater Glasgow
and Clyde

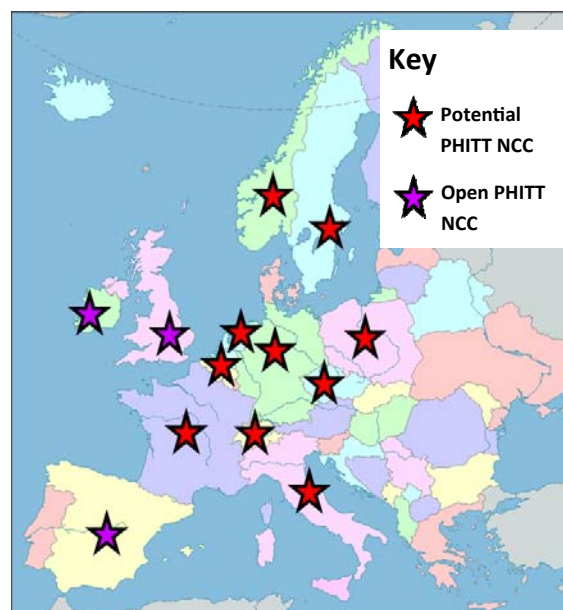
University Hospitals Bristol 
NHS Foundation Trust


Alder Hey Children's 
NHS Foundation Trust
Inspired by Children

It is hoped that the remaining UK hospital sites will be open by April 2018.

European National Coordinating Centres (NCCs)

There are 13 European countries who are partners in the ChiLTERN Project, that have agreed to be part of the PHITT Clinical Trial. These are Belgium (8 proposed sites), the Czech Republic (2 proposed sites), France (26 proposed sites), Germany (30 proposed sites), Republic of Ireland (1 proposed site), Italy (23 proposed sites), The Netherlands (1 proposed site), Norway (4 proposed sites), Poland (17 proposed sites), Spain (20 proposed sites), Sweden (6 proposed sites) and Switzerland (9 proposed sites), which along with the UK sites will give a potential total of over 160 sites to recruit patients.



Two of these NCCs are now open. These are:

The Republic of Ireland, opened on 07-Nov-2017;



Spain, opened on 30-Nov-2017.



It is hoped that the majority of the other NCCs will be open by April 2018.

The PHITT Trial also has interest from many other countries wanting to join, so it can expand even further!

Recruitment

At present there have been five patients recruited into the PHITT Clinical Trial, all recruited in November and December 2017. Royal Marston Hospital, Sutton, has recruited three patients, Royal Manchester Children's Hospital has recruited one patient and Bristol Royal Hospital for Children has recruited one patient.

PHITT Sample Kit - 'Remember to Collect Samples!'

Hospital site opens as part of the PHITT Clinical Trial.

Receives a PHITT Sample Kit from Childhood Liver Cancer Network (CLCN) bio-repository at IGTP, Barcelona, Spain (more on request).

Store in a fridge the 9 tubes that contain MACS medium as they should be stored at 4°C. These 50 mL tubes are the only ones with medium inside.

Tell PHITT Trial Office

Inform fellow PHITT work colleagues and local Pathology Laboratory. Make sure they understand the kit numbering system, as in which parts of the kit are designated for each part of the patients sample collection (see PHITT Laboratory Manual).

When samples have been collected from a patient, use the PHITT Patient Sample CRFs to complete the details about what samples have been taken. Post or email copies of partially completed forms, during treatment, and fully completed forms, at the end of treatment, back to the PHITT Trial Office.

At present, for the UK hospital sites, until the International Pathology Reviewer in Utrecht, The Netherlands, is up and running for the PHITT Clinical Trial, please send any patient samples preserved as FFPE blocks and HE/IHC Slides to the National Pathologist (Dr Jens Stahlschmidt, St James's University Hospital, Leeds, LS9 7TF, Email: jens.stahlschmidt@nhs.net), as well as Urgent Review patient samples.

Also, please tell the PHITT Trial Office what you think of the kits and about any problems with them.

ChiLTERN Collaborators' Meeting



A ChiLTERN Collaborators' Meeting was held at the Greater Birmingham Brussels Office in Brussels, Belgium, on the 29th November 2017. Amongst the topics discussed were amendments that need to be added to the PHITT Protocol. An amended version of the PHITT Protocol will be available at the beginning of 2018.

CONTACT DETAILS - PHITT TRIAL OFFICE

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