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.
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.

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

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](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](https://www.chilternproject.eu) for more details.
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.
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 ‘Yes’ gives a drop-down with two options: ‘Web system’ (using database) or ‘On phone (emergency Randomisation)’ (only used by Trial Office).

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

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