



From Left to Right:  
Professor Simon Gollins (CI),  
Dr Ane Appelt (CI) &  
Professor David Sebag-Montefiore  
(Clinical Director Leeds CTRU)

## Trial Status: April 2021 – July 2021

### Trial Update

Since the last newsletter in April 2021, the trial team have continued to work with sites on set-up and trial activities. We are happy to report that both Clatterbridge and North Tees have now opened to recruitment whilst Royal Devon have begun work on the set-up process for APHRODITE.

All sites are intended to open to recruitment as soon as possible, to help provide the best vital research to the patients at your site. We understand that there are immense difficulties at sites balancing COVID related activities, reopening existing trials and working towards setting up new trials and we would like to express thanks for all of your hard work.

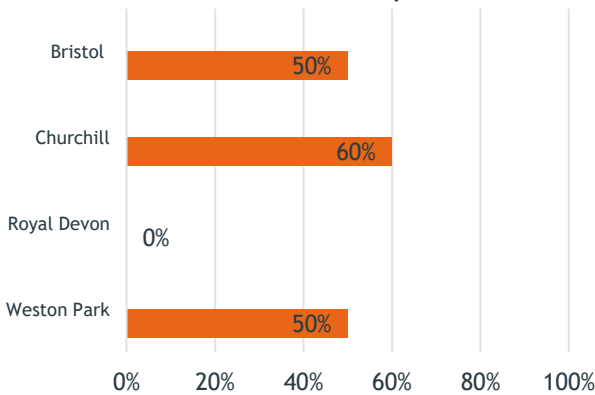
Substantial Amendment 2 has been approved and distributed to sites. This includes an amendment to the protocol and to the patient information sheet informed consent form (PISICF). Included in this are; an amendment to the GFR rate where patients who will take Capecitabine require more than or equal to 30ml/min creatinine clearance, a clarification of trial treatment definition, and an update to the statistical section. We also identified that the comparison of exposure from trial procedures to standard background radiation levels in the patient information sheet needed to be changed.

As has been mentioned previously, APHRODITE is changing the way we are collecting data from paper based CRFs to using mostly electronic CRFs (eCRFs). We are now in a position to begin collecting data via Remote Data Entry (RDE) allowing for easier data entry. CTRU should have already been in touch with more information on the transition to RDE, or will be shortly.

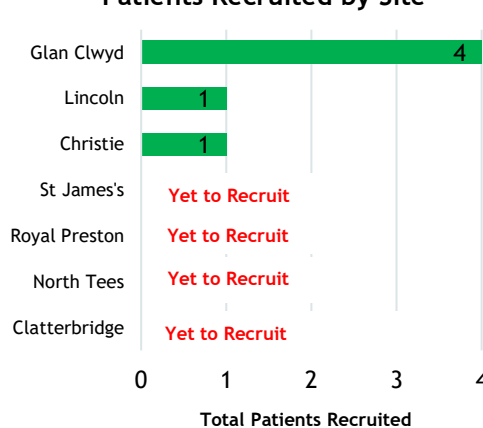
### Site Setup Status

All sites, with the exception of Royal Devon & Exeter, now have RTQA approval. Currently 7 out of the 11 sites are now open to recruitment and the remaining sites, as seen below, are more than halfway through the set-up process.

#### APHRODITE Sites in Set Up



#### Patients Recruited by Site



### Recruitment

Currently Glan Clwyd have randomised a total of 4 patients since opening. Lincoln and Christie have randomised 1 patient each. Royal Preston are actively screening patients but have yet to recruit, North Tees are the most recent site to open to recruitment.

Please can all sites remember to fill out the screening and non-recruitment log, this is vital for us to understand the amount of patients who are being screened and have not been eligible to take part in the trial. This will provide us with continuing information that we can provide to the senior trial team regarding the recruitment rate at each site.

Site	Date opened to recruitment	Most recent date halted recruitment	Most recent date reopened to recruitment	# days open to recruitment (- days trial on hold at site)	# of randomised patients	Date 1st patient randomised	Date of last randomisation	# of days from opening date to 1st randomisation
Glan Clwyd, North Wales	18/02/2020	19/03/2020	19/10/2020	205	4	24/02/2020	19/03/2021	6
Lincoln County Hospital	02/03/2020	19/03/2020	19/10/2020	192	1	13/01/2021	13/01/2021	16
Royal Preston	03/03/2020	22/01/2021	29/03/2021	300	0	N/A	N/A	N/A
Christie Hospital	15/03/2021	N/A	N/A	0	1	12/04/2021	12/04/2021	28

If you have any questions or queries about trial setup please contact the APHRODITE trial inbox.

Ask Matthew..?



**Matthew** is our Trial Management Assistant. He's happy to help answer any questions you may have.



Want to know more? Then please check out the twitter feed [https://twitter.com/aphrodite\\_trial](https://twitter.com/aphrodite_trial) for healthcare professionals.

Aphrodite Trial Team, CTRU  
From Left to right: Miss Rebecca Day, Dr Samantha Noutch & Mr Matthew Carter

If you would like your site to be featured on the newsletter then please let us know about your experience of recruiting into the APHRODITE trial!

