



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

## Trial Status: December 2020 – April 2021

### Trial Update

Since December 2020, following a pause to recruitment due to COVID-19, the trial team have been busy with the main focus of re-establishing communication with sites to resume work on trial activities. We are happy to report that although progress is slow we have made headway in opening the Christie in Manchester in March 2021 and St James's in Leeds in April 2021. We are also very close to opening Clatterbridge and North Tees.

We are aiming to have all sites open to recruitment, as soon as we possibly can, so we can best provide vital research to this patient population to your site. We understand that sites are under immense difficulties balancing COVID related activities, reopening existing trials and working towards setting up new trials. We would just like to express thanks for all of your hard work.

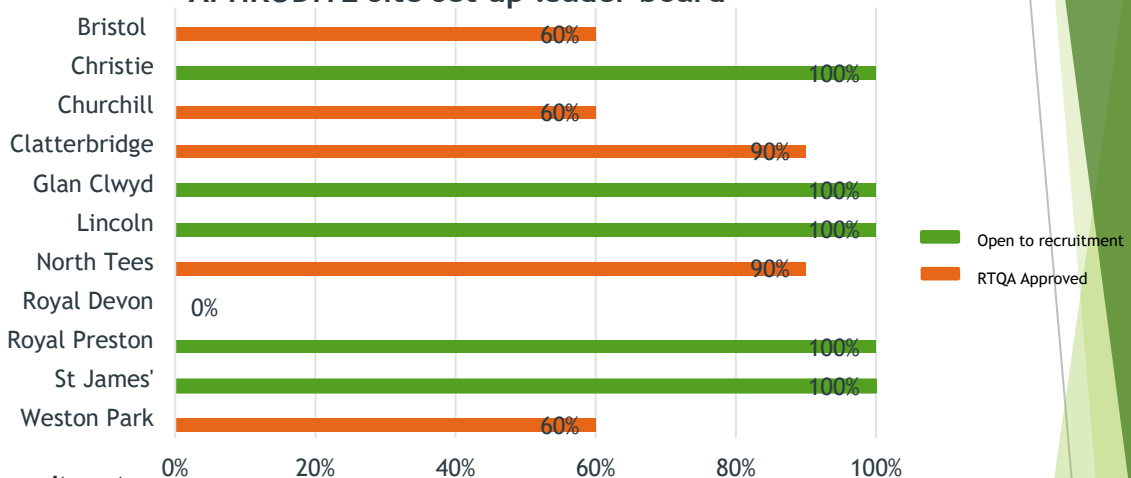
During the first quarter of 2021 we are currently undergoing a protocol amendment and an amendment to the patient information sheet informed consent form (PISICF). These changes include; an amendment to the GFR rate where patients who will take Capecitabine require more than or equal to 30ml/min creatinine 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. Once these documents have been approved, recruited patients will need to be re-consented using the PISICF.

The pandemic has given us the push to move APHRODITE to remote data Capture. This will make for an easier data entry and submission process both for sites and for the central CTRU trial team. The move is currently near finalisation and we will hopefully implement this in Q2 2021.

### Site Setup Status

All sites, with the exception of Royal Devon & Exeter, now have RTQA approval. Currently 5 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 site set up leader board



### 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, St James's are the most recent site to open to recruitment.

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 Nouch & 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!