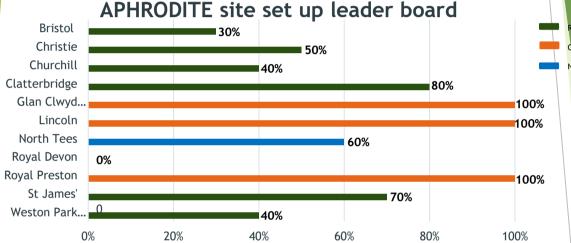


Site Newsletter Issue 3, December 2020

# APHRODITE has re-opened to recruitment!

### Trial Status – December 2020

We last communicated with you in March 2020 with much optimism and excitement. Glan Clwyd had recruited the first patient, Lincoln and Royal Preston had been given the green light to open to recruitment and the other sites were working tirelessly through the set-up process. However, following the onset of the COVID-19 pandemic a decision was made to suspend further recruitment in to APHRODITE and sadly our first patient was withdrawn and site set-up was put on hold. Over the summer we worked with sites to understand what the impact of the pandemic would mean for the future of APHRODITE – **thank to everyone who responded to our survey!** We then held a very successful meeting in October 2020 with sites and based on the feedback received a decision was made to reopen the trial to recruitment and recommence site set-up.



### Data Collection

We had originally intended to collect trial data using paper CRFs, however as a consequence of the COVID-19 pandemic APHRODITE will be transitioning to Remote Data Entry (RDE) for data capture. This will be released to sites in early 2021.

#### **Protocol Amendment**

Initial experience recruiting into APHRODITE has shown us that our GFR eligibility criteria have been too strict, in particular for patients who are to receive radiotherapy only. It has consequently been decided that the GFR eligibility criteria should be removed completely for any patients who will receive radiotherapy only, and lowered to <30ml/min for patients who will receive either Capecitabine or 5FU. This will require a substantial amendment to be submitted as soon as possible in the New Year. Please note that the current inclusion criteria are still in force until the amendment is in place.

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



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

Want to know more? Then please check out the twitter feed <u>https://twitter.com/aphrodite\_trial</u> for healthcare professionals.

## Happy Holidays from the APHRODITE Trial Team!

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





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



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

