

Introduction

On behalf of the Co-Chief Investigators, Professor Simon Gollins and Dr Ane Appelt and the CTRU Team, welcome to the 13th APHRODITE trial newsletter for May 2024! Thank you once again for all your continued hard work and recruiting into the APHRODITE trial.

Recruitment & Screening

Total recruitment to APHRODITE has reached **102** patients from across the 10 sites open to recruitment.

We have recruited **6** patients in May so far! In addition, **3** patients were recruited in one week in February and **3** patients were also recruited in one week in March!

A big congratulations to the **Christie** who recruited 3 patients in one week and have now recruited 33 patients in total!

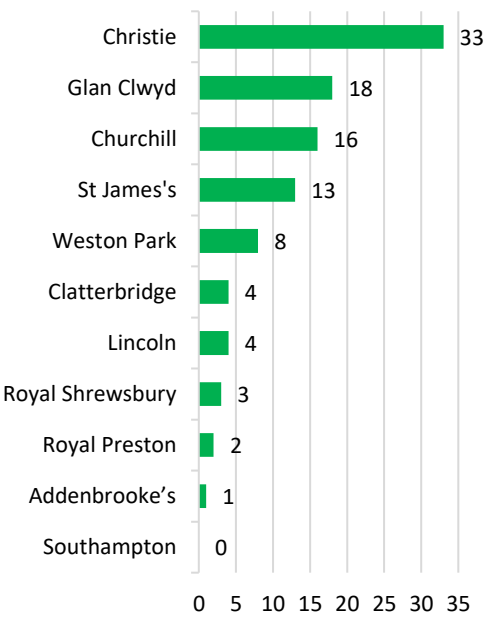
The graph to the right shows the total number of patients recruited per site, and the recruitment graph below shows the recruitment figures per month.

A **huge** congratulations to everyone that has recruited into the trial!

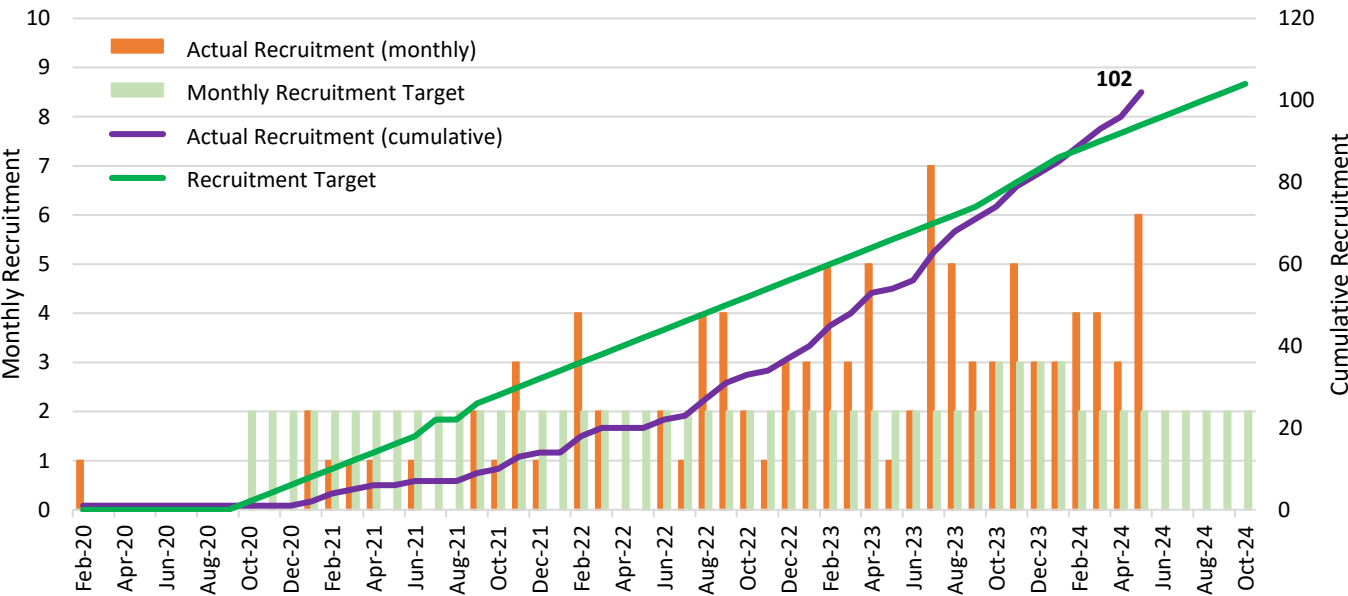
Our original target is to recruit **104** patients to APHRODITE from the 12 sites selected, however we are proposing a slight increase to the original target and continuing recruitment beyond 104. We will contact sites in **June 2024** once the Data Monitoring & Ethics Committee (DMEC) have discussed and agreed an updated recruitment target. An email was sent about this to sites.

We are now collecting screening logs for Q1 2024, an email was sent about this on the 4th April. Please make sure to use the most recent v2.0 log when completing any screening logs.

Total Patients Recruited per Site



APHRODITE Recruitment Figures



CRF & QoL Compliance

The CRF and QoL compliance for each site is shown in the table to the right.

Congratulations to **Addenbrooke's** for having the highest CRF and QoL compliance rate at 100%!

Site	CRF Compliance	QoL Compliance	Average Combined Compliance
Addenbrooke's	100%	100%	100%
Weston Park	99.10%	91.20%	95%
Royal Preston	100%	90.00%	95%
Lincoln	100%	88.50%	94%
Glan Clwyd	97.90%	84.00%	91%
St James's	98.20%	80.00%	89%
Christie	97.10%	79.30%	88%
Royal Shrewsbury	90.00%	66.70%	78%
Clatterbridge	88.50%	50.00%	69%
Churchill	66.00%	61.50%	64%

Extension and Non-Substantial Amendment 9 & 10

Following the trial securing a costed extension to the current grant from Yorkshire Cancer Research, the new recruitment end date is the **31st October 2024**, after which there will be a two-year follow-up and the trial will then end on the **30th April 2027**. The new end date for the trial was updated in non-substantial amendment 9 which was submitted on 1st February 2024 and sent to sites on the 2nd February 2024. Please note that approval for this amendment is not required as it is for notification only.

Another non-substantial amendment is currently in progress for two interim PIs, as well as an update to the trial summary so it contains the most up-to-date information and an update to the protocol regarding indemnity. Further information regarding both NSA9 and NSA10 is detailed in the table below.

	Date			Details
	Submitted	Approval received	Sent to sites	
NSA10	-	-	-	<ul style="list-style-type: none">• Arrangements to cover a PI absence at Addenbrooke's Hospital and Lincoln County Hospital.• Update to the trial summary with the most up-to-date information.• Protocol section 21 Statement of Indemnity has been updated to reflect the Sponsor insurance policy.
NSA9	24/01/2024	N/A	09/02/2024	<ul style="list-style-type: none">• The original recruitment and study end dates for the trial were the 30th April 2021 and 31st October 2023 respectively. However following the trial securing a no cost extension and a costed extension the new recruitment and study end dates for the trial are the 31st October 2024 and the 30th April 2027 respectively.

Discrete Choice Experiment (DCE)

The APHRODITE Patient Preference project is continuing to recruit participants, and we currently have **80** people who have completed the pre-treatment survey. We have also received six-month follow-up questionnaires from **38** participants already, and we are hoping to get more back soon.

We're still interested in opening more sites, so if you are not currently recruiting to the APHRODITE Patient Preference project and would like to get involved, please contact APHRODITEPatientPreference@leeds.ac.uk or e.j.d.webb@leeds.ac.uk.

If you have any questions or queries about trial setup, please contact Ella our Trial Management Assistant by emailing the APHRODITE trial inbox at APHRODITE@leeds.ac.uk

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!