

Introduction

On behalf of the Chief Investigators, Professor Simon Gollins and Dr Ane Appelt and the CTRU Team, welcome to the 11th APHRODITE trial newsletter for October 2023! Thank you once again for all your continued hard work and recruiting into the APHRODITE trial.

Recruitment & Screening

Total, total recruitment to APHRODITE has reached **73** patients from across the 11 sites open to recruitment. Our ultimate target is to recruit **104** patients to APHRODITE from the 12 sites selected.

We hit a recruitment record in July with **7** patients in July alone! A big congratulations to the Christie who recruited 3 patients!

Congratulations to **Southampton** for opening to recruitment! Further congratulations to **Addenbrooke's** and **Royal Shrewsbury** for opening to recruitment and recruiting their first patient!

Glan Clwyd and **Christie** both recruited particularly well in Q1 of 2023 with 3 patients each and Christie now having recruited 20 patients in total! The table to the right lists the total number of patients recruited per site.

We will soon be collecting screening logs for Q3 2023, an email will be sent about this in early October. Please make sure to use the most recent v2.0 log when completing any screening logs.

Site	Total Patients Recruited
Christie	22
Glan Clwyd	18
Churchill	10
Weston Park	7
St James's	6
Lincoln	4
Clatterbridge	2
Royal Preston	2
Addenbrooke's	1
Royal Shrewsbury	1
North Tees	0
Southampton	0

No-Cost Extension

A no-cost extension for the trial has now been approved. As such APHRODITE will now end on **30/04/2025** as opposed to the original predicted date of 30/04/2023. Recruitment and site setup will continue as previously so please continue to screen and recruit patients and complete site set-up requirements as necessary for your site.

Site Setup & Randomisation

We continue to support setup at sites opening to the trial. Please note telephone randomisation has been removed from APHRODITE as this system is being closed in 2023. Please make sure to randomise patients via the online randomisation portal <https://lictr.leeds.ac.uk/webbrand/> in future.

Endoscopy Central Review

As you will be aware, as part of the APHRODITE trial we are conducting an endoscopy central review for the first 2 patients to reach 6 months follow-up at each site. This central review process involves the submission of images of participant endoscopy procedures and a copy of the endoscopy report.

We have been experiencing problems with receiving images of poorer quality than we require however we understand it is difficult to ascertain the requirements we are after. Therefore, we have included some guidance and example images below to clarify the quality that we require the images to be in when sent to CTRU.

- Any photos sent for the central review need to be provided in colour and should be of the tumour site.
- The image should be clear and not dark.
- It is preferable that any photos sent should either be provided in a jpeg format, or embedded within a pdf document.
- Please also clearly label the photos with the date the endoscopic assessment took place and the patient trial ID.



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!



CI Move and Non-Substantial Amendment 6, 7 and 8

Please be aware that the Chief Investigator Professor Simon Gollins has moved from North Wales Cancer Treatment Centre to Shrewsbury and Telford Hospital NHS Trust. Following this the relevant study documents have been updated in the subsequent Non-Substantial Amendments 6, 7 and 8. In addition, an mNCA addendum has been approved which details the change in address of Professor Simon Gollins.

The changes made in each non-substantial amendment 6, 7 and 8 are summarised in the table below. Please ensure that following the sending of any amendments, that you confirm receipt by replying to the amendment email, as well as returning the signed PI Declarations requested. A reminder email will be sent to sites requesting outstanding PI declarations.

	Details
NSA6	Protocol updated for CI Professor Simon Gollins moving from North Wales Cancer Treatment Centre to Shrewsbury and Telford Hospital NHS Trust and change to their contact details.
	GP letter, Translational Manual and Trial Website updated for CI Simon Gollins' new contact details at Shrewsbury and Telford Hospital NHS Trust.
	Telephone randomisation removed as the CTRU have been moving away from using telephone randomisations as it is easier to test and set-up access online. The telephone system is being wound down and will be removed in 2023.
	Removed mention of Clavien-Dindo, a scoring of post-surgical complications as these complications are likely on a small sub-population and less relevant to collect for APHRODITE.
	GP Letter, Translational Manual and trial website updated for PI Simon Gollins' change in contact details.
	Professor Simon Gollins' email changed to Simon.gollins@nhs.net along with contact details.
	Dr Peter Mbanu to be the new PI at North Wales Cancer Centre.
NSA7	Royal Shrewsbury Hospital will be authorised to perform trial activities as a participating site. The PI will be Prof. Simon Gollins.
	Update to RTTQA team member James Iddenden's contact details due to move from Mount Vernon to Clatterbridge.
NSA8	Bristol will withdraw from the study and have not commenced with any recruitment activities.
	Royal Devon and Exeter will withdraw from the study and have not commenced with any recruitment activities.
	For new sites that will be added going forward a new version of the mNCA July 2022 will be used which will contain the Chief Investigator Professor Simon Gollins' new address and change in Sponsor Representative contact from Mrs Clare Skinner, who has now retired, and has now been replaced with Mrs Emma Armstrong. Existing sites that have already signed the original mNCA and are currently recruiting this notification of change of address and Sponsor Representative contact will be provided to each of these sites as an addendum.
	The protocol will undergo a change to update the CTRU's approach to retention of any copies of consent forms.
	The PISICF will undergo a change to update the CTRU's approach to retention of any copies of consent forms.
	The PISICF will undergo a change to update the Sponsor Representative contact from Mrs Clare Skinner, who has now retired, and has now been replaced with Mrs Emma Armstrong.

Discrete Choice Experiment (DCE)

The APHRODITE Patient Preference project is continuing to recruit participants, and we currently have **55** people who have completed the pre-treatment survey. We have also received six-month follow-up questionnaires from **30** participants already, and we are hoping to get more back soon. We are very pleased to have recently welcomed Christie to recruiting for the Patient Preference project alongside the trial. We are also hopeful of starting Patient Preference recruitment at Royal Shrewsbury 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.



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