



June 2023

Welcome to the first issue of the STARFISH Newsletter

Message from the Chief Investigators

The STARFISH trial has generated a lot of interest across the UK and we have been very grateful and impressed by the enthusiastic support of ENT consultants, associate specialists and trainees, as well as audiologists, nursing and research staff across the UK. The site initiation visits have been an excellent opportunity to engage with interested colleagues, and allowed us to troubleshoot some of the local or regional complexities of trial delivery.

As is often the case with large and complex trials we have had some delays in preparing to open centres. However now the trial machinery is fully in place site preparation is going well, and we are now in the exciting position of having many sites ready to open and start recruiting patients.

We are also pleased that so many trainees, nurses and audiologists have engaged in the NIHR Associate PI scheme and been accepted into this already, and expect this to be a valuable opportunity for them to acquire new skills, and to continue to build research capacity within our speciality.

We look forward to working with you all to deliver this exciting project.

Best wishes,

Mr Matthew Smith & Mr James Tysome



J. Lyson

Site Updates

We have had a fantastic response from sites all across the UK, registering expressions of interest in the STARFISH trial by completing the Feasibility and Practical Arrangements Form online - Thank You!

In total 70 sites have registered, from Ninewells in Scotland to Lincoln County in the East of England to Torbay in the South of England and to Royal Victoria Belfast in Northern Ireland.

We aim to open 75 sites in total across the UK, ideally with an ENT Consultant PI and an ENT Trainee Associate PI at each hospital.

For more information on the training and certification provided to associate PIs please visit: nih.ac.uk/AssociatePIScheme

Site Openings

We are over the moon to announce that the first four sites for the STARFISH trial are now open.

1st to open - Kettering General Hospital

2nd - Lister Hospital

3rd - Royal Bolton Hospital

4th - University College London Hospital

We would like to say a massive 'Thank You!' to all the site team members for your combined efforts and hard work to enable these sites to open, along with the site team members who are currently working on opening your sites.

The race is now on for the 1st patient!



Recruitment Map & Sites List

Click here to view the recruitment map & list of sites on the Starfish webpage.

[VIEW](#)

Site Initiations/ Q&A Sessions

Site initiations will be in the format of pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigators and trials office team, hosted on Zoom.

Site staff will be able to access the pre-recorded presentation online via [YouTube](#) or the [trial website](#) at their convenience.

You will be asked to self-certify that you have watched the pre-recorded video as evidence of trial training prior to joining a Q&A session. We will also be asking you to register for the Q&A session you will be attending; please do not share the Zoom meeting link details team colleagues, as the registration details will provide us with a record of attendees for report writing purposes.

The PI and any Associate PIs must do this before the trial can open at their centre, though we recommend that anyone involved in research activities for the trial does so too.

Q&A Session Information

The live Q&A sessions will be held regularly, so you can attend a session that suits you, though we would encourage you to join together as a team where you can.

- 1st Monday in month 09:00 – 09:30 am
- 3rd Tuesday in month 10:30 – 11:00 am
- 4th Tuesday in month 08:30 – 09:00 am
- 5th Tuesday in month 08:30 – 09:00 am

Tuesday 27th June 2023, 08:30 - 09:00 am

Monday 3rd July 2023, 09:00 - 09:30 am

Tuesday 18th July 2023, 10:30 - 11:00 am

Tuesday 25th July 2023, 08:30 - 09:00 am

Monday 7th August 2023, 09:00 - 09:30 am

Please register for a Site Q&A session [here](#)

What Do I Need Before The Trial Can Open At My Centre?

Current CVs (signed within the last 12 months): required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site.

<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>

Good Clinical Practice (GCP) certificates: required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site. Please find GCP Certificate link below:

<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

Study specific training including the pre-recorded SIV presentation: Required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site. Please find the training system link below:

[STARFISH e-training link](#)

The training videos can also be accessed via the trial website:

<https://www.birmingham.ac.uk/starfish/training>

Attendance at a live virtual Q&A session: Required for the PI and Associate PI prior to opening, but we recommend anyone involved in trial delivery attends.

Registration information is available on the trial website, here:

<https://www.birmingham.ac.uk/research/bctu/trials/renal/starfish/trial-resources.aspx>.

Completed Delegation log (v2.0, 15-Dec-2022). A blank copy is available at the following link:

<https://www.birmingham.ac.uk/documents/college-mds/trials/bctu/starfish/starfish-site-delegation-log-v2.0-15-dec-2022.pdf>

Protocol signature page, signed by the PI (v3.0, 10-Oct-2022)

NIHR Associate PI Scheme

People who would not normally have the opportunity to take part in clinical research in their day to day role have the chance to experience what it means to work on and deliver a NIHR portfolio trial under the mentorship of an enthusiastic Local PI.

Participating healthcare professionals receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

For more information visit: nihr.ac.uk/AssociatePIScheme

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