



STARFISH



Newsletter

Winter 2025

In This Edition:

Message from the CI's

Study Updates & Milestones

Open sites

Screening and recruitment update

HearX home hearing tests

Successful patient engagement for the STARFISH trial

An update from Rachel Knappett's talk at BAA

Trial Awareness & Training

STARFISH departmental slides for team training

Q&A sessions

Delegation Log update

Associate PI scheme

An offer of authorship to all resident doctors and Audiologists at STARFISH sites.

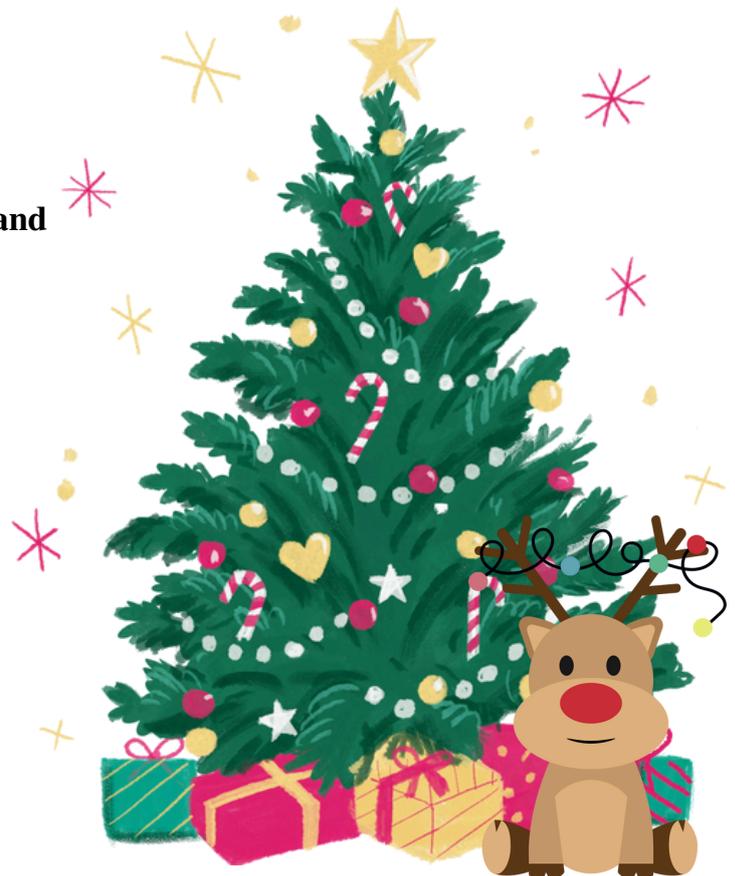
Patient Information Sheet Reminder

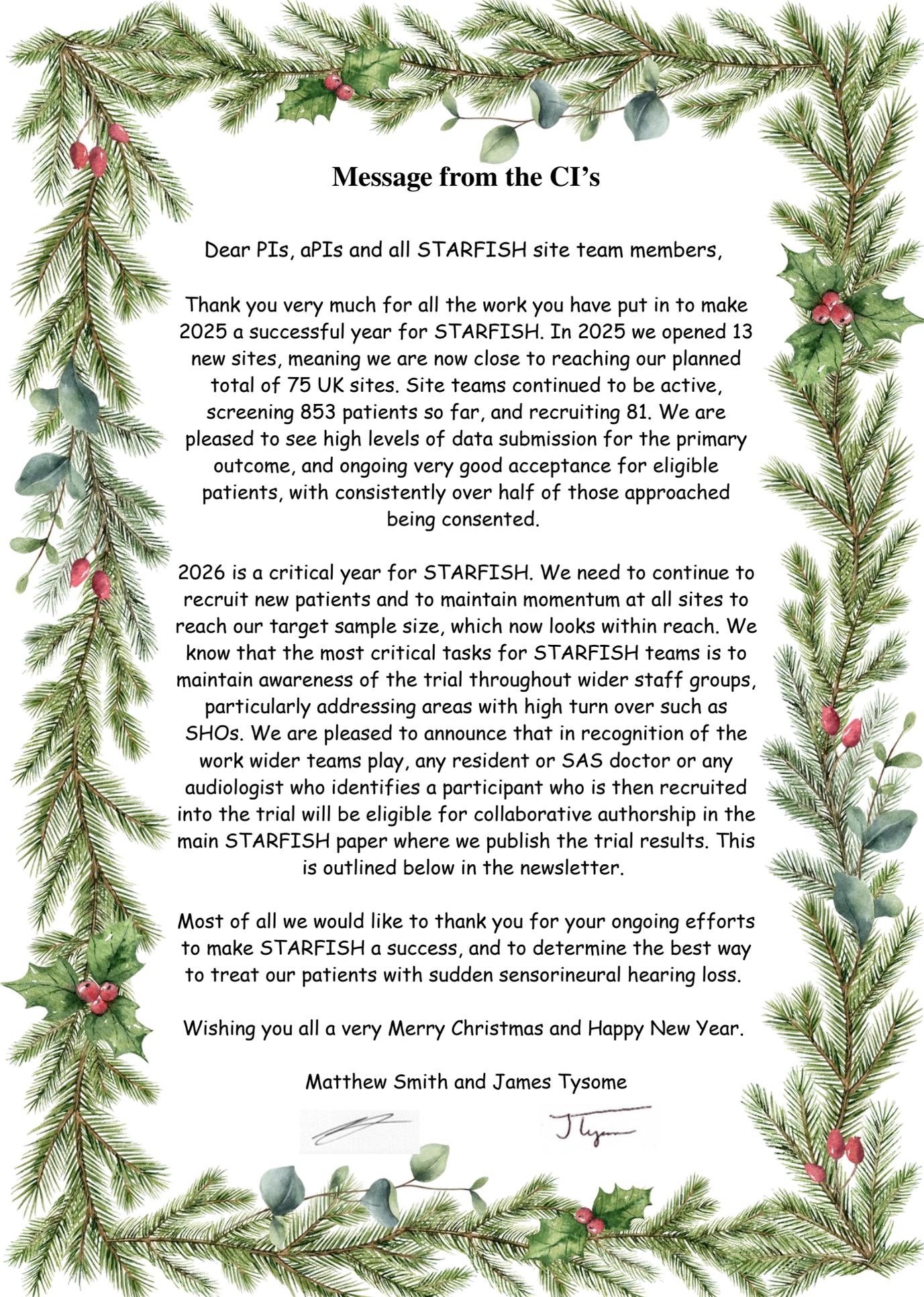
A Few Facts & Figures!

CRF Returns

Hints & Tips

Christmas Closure & SAE Reporting





Message from the CI's

Dear PIs, aPIs and all STARFISH site team members,

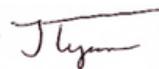
Thank you very much for all the work you have put in to make 2025 a successful year for STARFISH. In 2025 we opened 13 new sites, meaning we are now close to reaching our planned total of 75 UK sites. Site teams continued to be active, screening 853 patients so far, and recruiting 81. We are pleased to see high levels of data submission for the primary outcome, and ongoing very good acceptance for eligible patients, with consistently over half of those approached being consented.

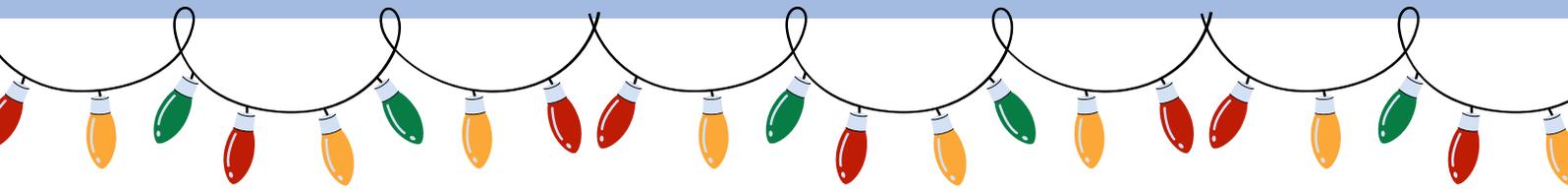
2026 is a critical year for STARFISH. We need to continue to recruit new patients and to maintain momentum at all sites to reach our target sample size, which now looks within reach. We know that the most critical tasks for STARFISH teams is to maintain awareness of the trial throughout wider staff groups, particularly addressing areas with high turn over such as SHOs. We are pleased to announce that in recognition of the work wider teams play, any resident or SAS doctor or any audiologist who identifies a participant who is then recruited into the trial will be eligible for collaborative authorship in the main STARFISH paper where we publish the trial results. This is outlined below in the newsletter.

Most of all we would like to thank you for your ongoing efforts to make STARFISH a success, and to determine the best way to treat our patients with sudden sensorineural hearing loss.

Wishing you all a very Merry Christmas and Happy New Year.

Matthew Smith and James Tysome





Study Updates & Milestones

We would like to say a continuing ‘Thank You!’ to all the site team members for your support and hard work enabling us to open **70** sites to date, along with a further 3 in set-up and 2 that have shown an expression of interest. Target of **75** sites almost reached!

Patients screened to date: over **1600**

Patients recruited to date: **217**

March 2024: Best recruitment month (18)

March 2025: Best screening month (103)

Congratulations to **UCLH** for being the top screening site with 381 patients.
Congratulations to **Addenbrooke's** for being the top recruiting site with 19 patients

We would also like to give a ‘Special mention’ to the following sites that have now recruited beyond their initial target:

Countess of Chester Hospital, Liverpool
Queens Medical Centre, Nottingham
Sandwell General Hospital, Birmingham

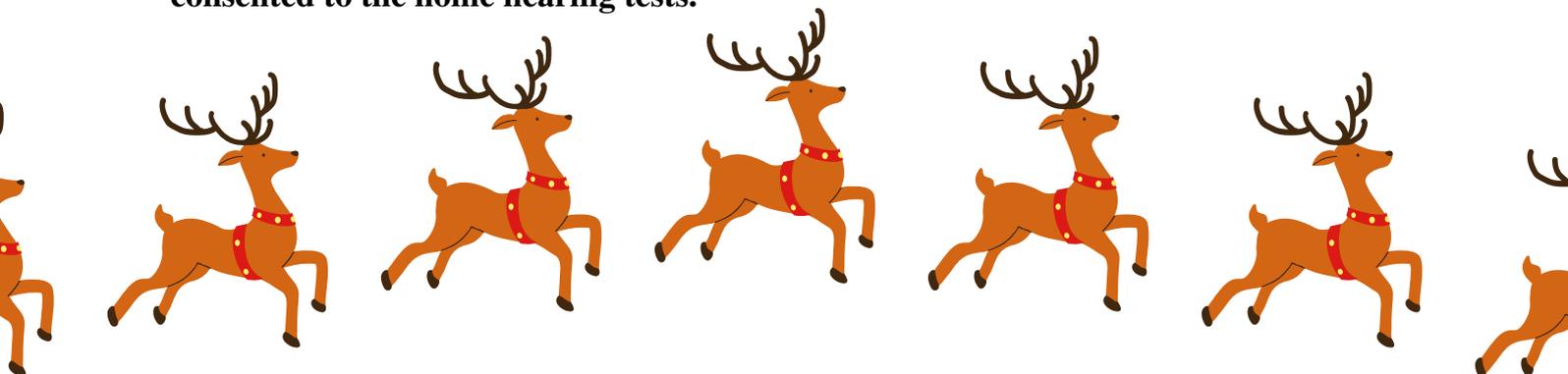
Screening Reminder

Please remember we require all patients that have been screened to be entered onto the Screening Log, even if ineligible.

HearX Home Hearing Tests

Since the tests were rolled out in June participants have been taking part, ‘Thank You’ to the sites that have organised this. Please continue to encourage all team members sites to discuss this with any newly randomised patients, when issuing the Participants Packs.

Sites will be contacted with a reminder when a new patient is randomised and have consented to the home hearing tests.





Successful patient engagement for the STARFISH trial



Clinical trial recruitment can often be challenging!

The way a clinical trial is discussed with a potential patient can greatly impact on whether the patient decides to take part in the trial or not.

The information given to the patient should be clear, simple, jargon-free communication, focusing on the trial's purpose, risks, benefits, procedures and committal time, while emphasizing that participation is totally voluntary and they can withdraw at any time. Current treatments can be discussed and how the trial interventions differ if applicable.

A number of sites have recently asked for advice how to communicate with potential patients effectively.

Please see some **'Top Tips'** below:

- Explain that all three STARFISH treatment arms are standard treatments used in the NHS, nothing is 'experimental' or new
- We do not know which treatment will work best, which is why this study is needed. All have different mostly minor risks and drawbacks, but every patient receives evidence-based steroid therapy
- Being part of STARFISH in most cases does not require additional hospital trips, beyond those needed for the standard interventions and follow up
- Highlight that the only extra hearing test needed in follow up appointments is a speech test, which many patients find best reflects their hearing performance and allows them to track progress



Trial Awareness & Training

With the continuing the need of in-house team awareness of the trial, please encourage as many staff members to be added to the Delegation Log as possible.

Please see the link below to the STARFISH Departmental Slides which can be used for internal training of new team members.

<https://entintegrate.co.uk/wp-content/uploads/2024/10/STARFISH-Departmental-Presentation.pdf>

Q&A Sessions

Site initiations continue to be in the format of a pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigators and trials office team, hosted on Zoom. This is mandatory for the PI and Associate PI, although we recommend that anyone involved in research activities for the trial attends too.

Site staff can access the pre-recorded presentation online via **YouTube** or the **trial website** at their convenience.

Sessions are held on the following days:

- 1st Monday of the month – 10:00-10:30

To see all forthcoming session dates, please register **here**.

- 3rd Tuesday of the month – 10:30-11:00

To see all forthcoming session dates, please register **here**.



We also welcome members of site staff that may be struggling to screen or recruit patients, to re-attend a Q&A session to discuss steps that other sites may have taken to overcome any barriers they have experienced.

Delegation Log Update

We would like to stress the importance of updating the Delegation Log when people join the team or no longer work on the trial. This also helps us to keep our contacts up to date so all team members are included in any important correspondence.

Associate PI Scheme

The NIHR Associate PI Scheme is still open for registrations for the STARFISH trial.

The scheme is open to any healthcare professional willing to make a significant contribution to the conduct and delivery of a study at a local level over a period of six months, this opportunity is ideally suited to any ENT Specialist Trainee, though an Audiologist or nurse could also take on the role too.

We currently have the highest number of registrations for any ENT trial (currently 120+ registrations).





An offer of authorship to all resident doctors and Audiologists at STARFISH sites.

We are keen to increase recruitment to STARFISH. Starting from 15 December 2025, we are offering the opportunity for all resident resident or SAS doctor or Audiologists who recruit a patient to STARFISH to be included in the collaborative authorship on the paper that will be published once the trial concludes. We hope that this will encourage colleagues to recruit patients to the trial by identifying them to your local team who are co-ordinating the trial.

If a patient is successfully recruited, please email Karen James, STARFISH Trial Manager, at STARFISH@trials.bham.ac.uk and copy in the Principal Investigator or Associate Principal Investigator at your site so that they can confirm that you are responsible for recruiting a patient.

Not only is this an opportunity to be involved in a NIHR funded RCT, but you also get to be an author on the main paper that will be published to report the results of the trial.





STARFISH: Participant Information Sheet



<local headed letterhead>

Participant Information Sheet

STARFISH: STeroid Administration Routes For Idiopathic Sudden Sensorineural Hearing Loss

An introduction

The patients who are working with us on this study have stressed how extremely distressing and debilitating sudden unexplained hearing loss has been for them and so we appreciate how anxious you are feeling. To go abruptly from normal hearing to sudden deafness, possibly with dizziness and ringing in your ears is very disturbing. The big question for all our patients is "Will I get my hearing back?". While we cannot promise you that treatment will restore your hearing, we want to reassure you that there are some things which can be done for you and treatment is available.

Whilst the causes of this form of hearing loss are not well understood, we do have steroid treatments that can be effective in restoring your lost hearing. These treatments are used regularly in the NHS and include:

- 1) Steroid tablets taken by mouth
- 2) Steroid injections
- 3) A combination of both the above

Currently the treatment you are offered will vary depending on where and when you are treated. Our challenge is that we don't yet know which is the most effective way to give you the steroids to get the best hearing recovery.

This is where this trial comes in. Our team aims to find out which of the different steroid treatments works best in improving the hearing of patients suffering from your type of hearing loss. The trial will take a group of patients and assign them randomly to one of the three treatment methods commonly used. We will then track their hearing recovery, as well as measuring the impact of the hearing loss on the participants' lives with questionnaires.

If you are interested in taking part in this trial, this sheet and a team member will now explain the exact details and what it will mean for you and then you can decide if you would like to take part. Don't worry, joining the STARFISH study is voluntary and if you decide not to participate you will still receive our best care and the treatment we normally offer at this hospital.

Patient Information Sheet Reminder

We would like to remind all sites that the current version of the Patient Information Sheet that should be used is **v4.0, 25-Oct-2024**

There have been a small number of incidences where the wrong version of the form has either been given to the patient or indicated on the Consent Form, resulting in File Notes to document the errors.



A Few Facts & Figures!

While it's obviously impossible to put into words exactly how much effort has been put into this study by all of the teams across the dozens of recruiting sites, some incredibly impressive numbers help put some perspective on the study and just how much work has been put into it:

STARFISH trial has been open for **30 months**

70 sites currently open

Over **800** site staff across the UK - including Consultants, Trainees, Research Nurses, Audiologists, Research Governance staff, admin staff

1500 CRFs have been completed

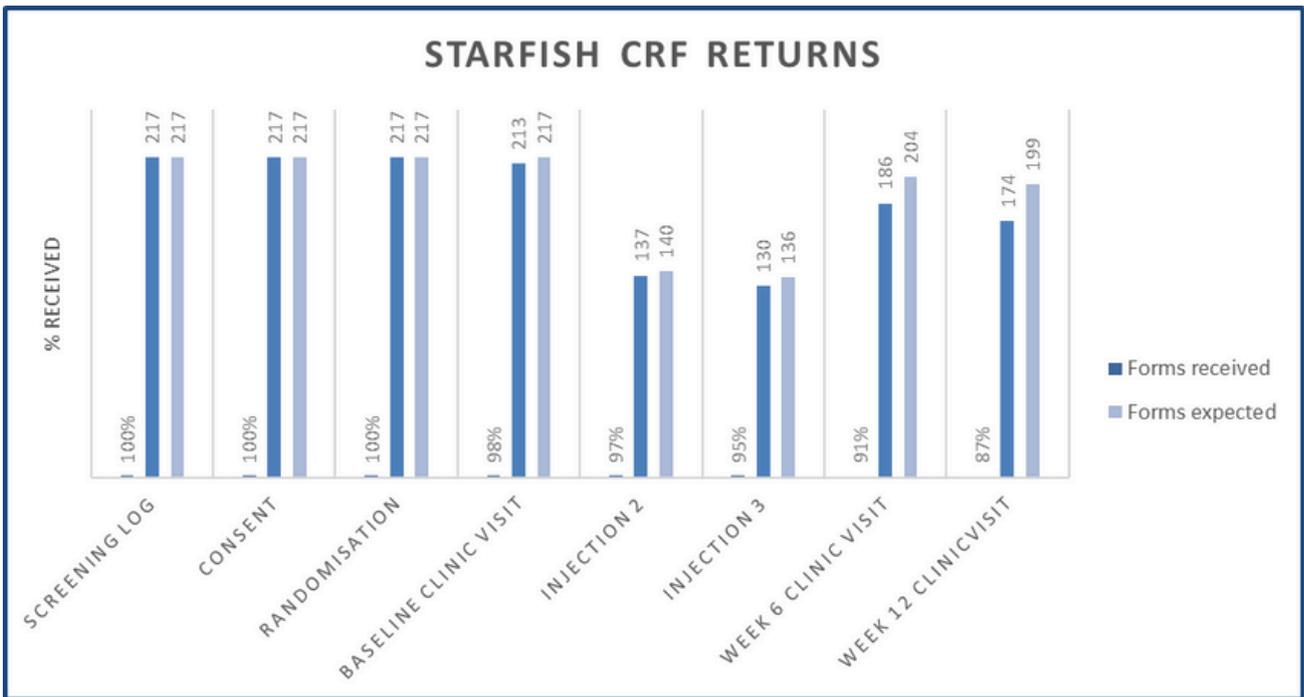
2500 queries raised and resolved





CRF Return

Thank you to all sites for your continued support in completing CRFs on the STARFISH database in a timely manner; the current return rate is over **96%**





Hints & Tips

We have found that sites who are in a WhatsApp group together can stay in touch with members of staff about the STARFISH trial and any potential patients, hence aids recruitment

CRF completion — common errors:

- Remember to complete 'Section 3 - Patient approach' at the end of the Screening Log for **ALL** screened patients
- **PIs remember to complete the 'Form Completed By & Sign Off' and 'Principal Investigator' sections of the Randomisation and Clinic Visit Forms. Both fields require PI sign off (located at the bottom of respective forms)**
- Ensure that if a patient questionnaire booklet is not completed, it is marked as 'No' on the relevant Clinic Visit Form, this will stop you receiving repeat missing booklet reminders
- Ensure that **ALL** Clinic Visit Forms are completed. If the visit did not occur still complete and add the reason why
- **Please could all sites ensure that the Baseline Clinic Visit form is completed for all patients**

N.B. if the Week 12 Clinic Visit Form is not completed this will impact on the patient payment being made





Christmas Closure & SAE Reporting

Birmingham Clinical Trials Unit (BCTU) and the University of Birmingham will be closed from **16:00, Monday 22nd December 2025 until 08:00, Friday 2nd January 2026**

The STARFISH online database (<https://starfish.bctu.bham.ac.uk/>) will be available over the Christmas period

The STARFISH mailbox (STARFISH@trials.bham.ac.uk) will be monitored periodically over the Christmas period; if your query is urgent and requires an immediate response, please include 'URGENT' in the subject line of the email, otherwise we will respond on our return

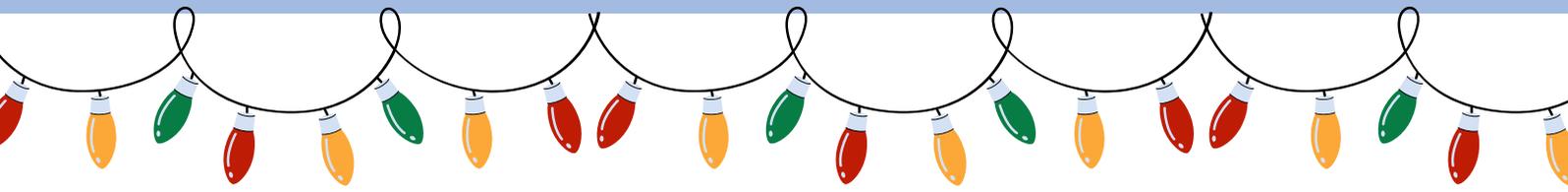
SAEs should be reported in the usual manner, as per the SAE Reporting Guidelines which can be found in section 13.1 of the ISF or via the website link:
www.birmingham.ac.uk/research/bctu/trials/renal/starfish/starfish-database.aspx

Please ensure that the causality assessment is made and reported by a medically qualified doctor as soon as possible

Let's continue to raise awareness and improve outcomes together –
thank you for helping us make STARFISH a success!

 **MERRY
CHRISTMAS** 





STARFISH Chief Investigators:

Dr James Tysome
Addenbrooke's Hospital
jrt20@cam.ac.uk

Dr Matt Smith
Addenbrooke's Hospital
mes39@cam.ac.uk

STARFISH Team Leader:

Liz Brettell
e.a.brettell@bham.ac.uk

STARFISH Trial Manager:

Karen James
k.e.james@bham.ac.uk

STARFISH Data Manager:

Brendan Smith
b.smith.7@bham.ac.uk



STARFISH@trials.bham.ac.uk
0121 415 9131
STARFISH Trial Office
Public Health Building (Y17)
University of Birmingham
Edgbaston
Birmingham B15 2TT



UNIVERSITY OF
BIRMINGHAM

