

# STARFISH

## Newsletter



*In This Edition:*

### **Updates & Milestones**

**Open sites**

**Screening and recruitment update**

**HearX home hearing tests**

**A 'Thank You' from the STARFISH Senior Statistician**

**Successful patient engagement for the STARFISH trial**

**Offer of authorship reminder**

**Trial Awareness & Training**

**Delegation Log update**

**Q&A sessions**

**STARFISH Database**

**Associate PI scheme**

**Reminder to Patients about unblinding**

**Hints & Tips**

**STARFISH Feedback from the frontline!**

**Easter closure & SAE reporting**

# Study Updates & Milestones

## Open Sites

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 **71** 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!



A map of hospital sites that have expressed an interest in the STARFISH trial, in site set-up or open

**Blue marker** - sites that have shown expression of interest

**Orange marker** - sites in set-up

**Green marker** - sites open to recruitment

# Screening and Recruitment Update

Patients screened to date: over **1800**

Patients recruited to date: **246**

March 2024: Best recruitment month (18)

March 2025: Best screening month (103)

Congratulations to **UCLH** for being the top screening site with **456** patients.

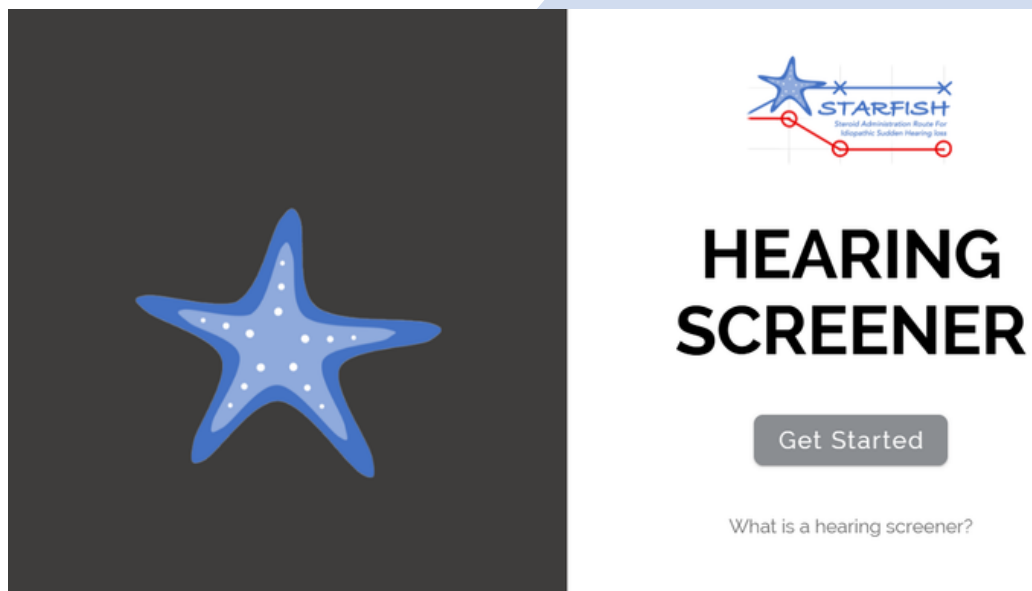
Congratulations to **Addenbrooke's** for being the top recruiting site with **22** patients

While recruitment is currently planned to end in November 2026, we are opening discussions with the NIHR to keep the trial open as it is likely that we will need to continue recruiting until January 2028.

## 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 2025 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.**

# A 'Thank You' from the STARFISH Senior Statistician

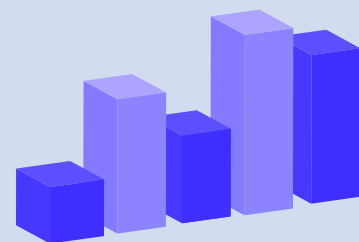
Typically for clinical trials, formal data cleaning and querying only occurs when there are interim analyses for data monitoring committee meetings or at the end if for final analysis. The schedule of interim meeting for most trials are only once a year and so in most studies no data queries are raised until the point of the interim analysis. But this leads to a mass generation of data queries to be clarified ahead of these formal analysis and puts a lot of time-pressure for trial management teams to raise the queries with the respective sites and ultimately burdening those sites with a flurry of queries all at once, with possibility some queries relating to patients recruited almost a year ago.

To avoid this, since the STARFISH trial began recruiting in June 2023, we have undertaken 30 rounds of data cleaning and queries activities (in other words means querying the data every month). Your timely resolution of these queries has resulted in enabling us to maintain a very clean database throughout, but more importantly this has meant we have been able to significantly reduce the workload with respect to the number of queries raised for any formal interim analyses.



As the senior statistician for the STARFISH trial, I would like to express my sincere gratitude for your continued involvement in firstly recruiting to this trial, but also for your continued support with the regular resolution of the queries we have been raising. With this continuation by the end of the study, this will lead to a quicker locking of the database for final analysis and ultimately a timely completion and reporting of the trial.

Samir Mehta (MSc)  
Senior Medical Statistician  
Birmingham Clinical Trials Unit (BCTU)



# Successful Patient Engagement

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



# Offer of Authorship Reminder



We are keen to increase recruitment to STARFISH. Starting from 15 December 2025, we are offering the opportunity for all resident doctors, 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](mailto: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.



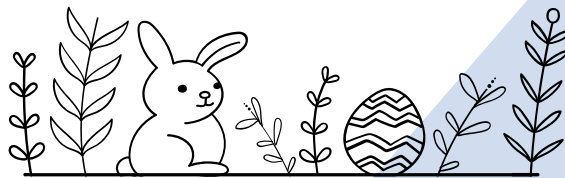
# Trial Awareness & Training

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>

If all sites could recruit 1 patient, we would be able to close the study reaching our recruitment goal!



## Delegation Log Update

We would like to emphasize the importance of updating the Delegation Log **in real time** whenever team members join or leave the trial.

Maintaining an accurate and up-to-date log ensures that our contact records remain current, allowing all relevant team members to be included in important communications.

Thank you for your cooperation.



# 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:

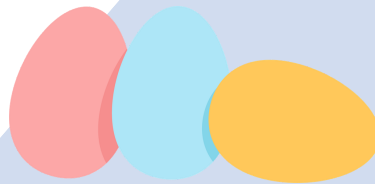
- 1st Monday of the month – 10:00-10:30

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.**



## STARFISH Database

Could we kindly ask that once you receive your database account details, you set up your password, log in, and take some time to familiarise yourself with the system in advance of any patient being recruited into the trial.

We have encountered a few instances where this has been left until the day a potential patient is identified, which has unfortunately led to account access issues. This can create unnecessary pressure for the randomiser and, in some cases, may risk losing the patient. Completing this process ahead of time will also allow us to identify and resolve any issues promptly, ensuring a smooth process when recruitment occurs.



# Associate PI Scheme

The NIHR Associate PI Scheme (aPI) 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).

**IMPORTANT** - Please note that being added to the Delegation Log, submitting requested documents, or beginning work on the trial does not automatically register you as an aPI.

To be recognised as an aPI, you must register separately for the NIHR Associate PI Scheme, which runs for six months. Regular reminders are circulated regarding this requirement.

The trial team will receive confirmation once an individual has both registered for and completed the scheme. This is confirmed through submission of the aPI Status Checklist, **which must be signed by the aPI, the Principal Investigator (PI), and the Trial Manager (Karen James).**

If you believe you have already been working as an aPI, but have not registered for the scheme, please contact the Associate PI Scheme team directly at:

[associatepischeme@nihr.ac.uk](mailto:associatepischeme@nihr.ac.uk) for further assistance.



# Reminder to Patients about unblinding

We would like to remind all sites to ensure that patients do not disclose or “unblind” their trial treatment to the Audiologist conducting assessments for the STARFISH trial.

It is essential that the Audiologist remains blinded to the trial treatment at all times. Any instance where blinding is compromised will require recording as a protocol deviation.



## 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
- **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**

# STARFISH Feedback - from the frontline!



University College London Hospital



Hafiz Elshazali - Clinical Research Fellow  
Roulla Katiri - Clinical Research Audiologist

Roulla Katiri, a Clinical Research Audiologist from University College London Hospital, shares that she has found STARFISH to be one of the most rewarding clinical trials to deliver.

*‘STARFISH brings clinicians closer to the immediate impact of their work. Working alongside Hafiz Elshazali, Clinical Research Fellow and the STARFISH aPI at UCLH, we value how STARFISH empowers ENT SHOs and audiologists to build confidence in getting involved in clinical research, and see patients benefit in real time.’*

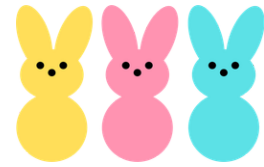
*‘Both highlight the strong team spirit the study creates, the quick wins, shared milestones, and visible recognition for staff who go the extra mile to identify a participant. STARFISH is not just a study but a motivating, energising way to embed research in everyday clinical practice.’*

*‘Additionally, a patient with sudden-onset sensorineural hearing loss asked me to pass on her sincere thanks. She was extremely impressed by how quickly she was contacted by our ENT SHO, and by how efficiently her visit to the Urgent Referral Clinic was organised. She commented that the whole process felt very smooth and that everyone she met was kind, helpful, and reassuring. She was very grateful for the excellent care she received.’*

Great to hear, thanks Roulla!



# Easter Closure & SAE Reporting



Birmingham Clinical Trials Unit (BCTU) and the University of Birmingham will be closed from **16:00, Thursday 2<sup>nd</sup> April 2026 until 08:00, Thursday 9<sup>th</sup> April 2026**

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

The STARFISH mailbox ([STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)) will be monitored periodically over the Easter 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](http://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

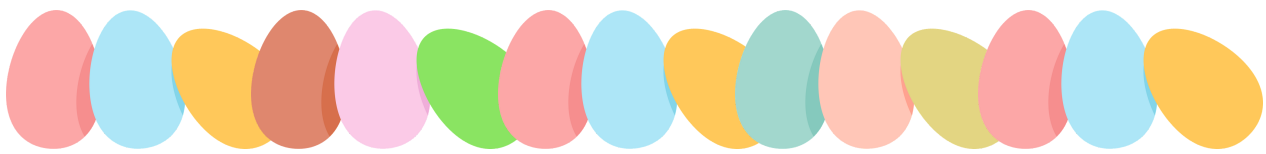
## Emailing STARFISH

We endeavour to respond to emails as promptly as possible. To help us maintain efficient and timely communication across all sites, we kindly request that all correspondence is sent to the STARFISH mailbox ([STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)).

If you are emailing the Trial Manager (Karen James) or the Data Manager (Brendan Smith) directly, please ensure the STARFISH mailbox is always cc'd.

This will help ensure your query is addressed promptly, even in the event of staff absence.





**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

