

# STARFISH

## Newsletter



### *Spring 2025*

*In This Edition:*

#### **Study Updates & Milestones**

- 58 sites open, 1000+ patients screened, 168 recruited.
- March 2024: Best recruitment month (18).
- March 2025: Best screening month (103).
- Top Screening Site: UCLH (214 patients)
- Top Recruiting Site: Addenbrooke's (15 patients)



#### **Training & Engagement**

- **STARFISH departmental slides for team training**
- Upcoming Q&A sessions – 1st Monday (10:00), 3rd Tuesday (10:30)
- **Register for a session**

#### **Associate PI Scheme**

- 100+ aPI registrations – a record for ENT trials!
- Open to ENT trainees, audiologists, nurses.
- **More info on the NIHR aPI scheme**

#### **Primary Care Engagement: New Resources Launched!**

#### **Hints & Tips**

- WhatsApp group = better communication
- Remember to sign CRFs properly and mark incomplete questionnaires
- Week 12 form essential for patient payments

#### **Patient Video Coming Soon!**

- STARFISH patient & CI video to be released at NIHR event
- Easter Closure Notice
- Closed: 17–24 April 2025
- Online database remains available
- Continue SAE reporting per guidance



We would like to say a massive ‘Thank You!’ to all the site team members for your support and hard work enabling us to open **58** sites to date, along with a further **10** in set-up and **12** that have shown an expression of interest.

To date you have screened over **1000** patients and recruited **168** into the STARFISH trial. March 2025 was the best month for screening patients with **103** screened.

Congratulations to **UCLH** for being the top screening site with **214** patients.

Congratulations to **Addenbrooke's** for being the top recruiting site with **15** patients.

### **Screening Reminder**

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

A thank you to all the engaged sites that took part in the 1:1 meetings, this was found to be very valuable in recognising the differing pathways on how the patients enter the trial (either GP referral, after being seen at A&E or from patients actively seeking out the trial themselves).

It also highlighted the need of greater in-house team awareness of the trial and adding as many staff members 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.

#### **STARFISH Departmental Slides:**

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

STARFISH was recently represented at the East of England primary care forum. Practices in this area are now paid study support costs for participating

Recent publication in the March 2025 InnovAiT journal (**Pages 155 - 159**):

[https://europe.nextbook.com/nxteu/sageuk/innovait\\_202503/index.php?startid=158#/p/154](https://europe.nextbook.com/nxteu/sageuk/innovait_202503/index.php?startid=158#/p/154)

## Site 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.

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.

**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.**

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

- 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](#).



## Associate PI Scheme

We would like to remind you that the NIHR CRN Associate PI Scheme (Portfolio CPMS ID: 53517) 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 at least six months and for STARFISH **this opportunity is ideally suited to an ENT Specialist Trainee, though an Audiologist or nurse could also take on the role too.**

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.

**We currently have the highest number of registrations for any ENT trial (currently 100+ registrations). As confirmed by the NIHR aPI scheme team, ‘STARFISH has completely revolutionised the number of trainees applying for the scheme with a far higher number registering for an ENT trial than has been previously seen.’ Due to this success we have been able to recruit PIs at sites that are not usually research active and support them to deliver the trial. We hope this will encourage participation of others at our STARFISH sites.**

For more information visit: [nhr.ac.uk/AssociatePIScheme](https://nhr.ac.uk/AssociatePIScheme)



## Primary Care Engagement: New Resources Launched!

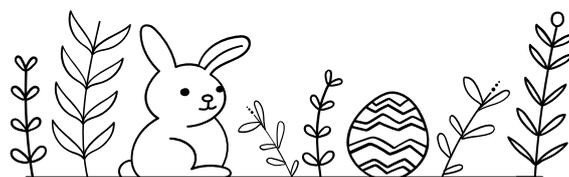
We are pleased to announce the launch of new STARFISH study support materials specifically designed for primary care! These resources include an interactive “Pop-Up” feature that seamlessly integrates with GP IT systems, visually appealing posters and memorabilia for your GP surgery, as well as concise video guides on assessing and managing patients with sudden sensorineural hearing loss (SSNHL). These tools are intended to support earlier identification and referral of eligible patients, a vital step in ensuring equitable access to this important trial.

We appreciate the growing interest within primary care, particularly among our colleagues in the East of England, where study support costs are now available for participating practices. This announcement was made during the regional primary care research forum on 12 March 2025. To access these resources, please reach out to your local RRDN. Our primary care engagement lead, Dr. Serge Engamba, is available for meetings, presentations, and tailored discussions regarding primary care participation. Please feel free to contact us with any questions.

Explore our resources and training materials by clicking here:

- [How to assess SSNHL in primary care \(2 min\)](#)
- [Tuning fork tests in SSNHL \(55 sec\)](#)

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



## 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.

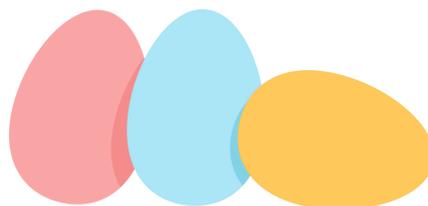
CRF completion — common errors:

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

**Please could all sites ensure that the Baseline Clinic Visit form is completed for all patients.**

## CRF Returns

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 **92%**





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